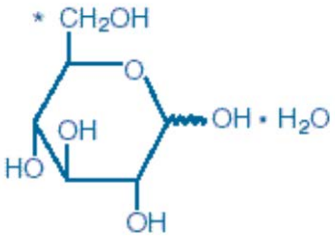
Lactated Ringer's and 5% Dextrose Injection, USP

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 Hydrous, USP*; 600 mg Sodium Chloride, USP (NaCl); 310 mg Sodium Lactate ($C_3H_5NaO_3$); 30 mg of Potassium Chloride, USP (KCl); and 20 mg Calcium Chloride, USP ($CaCl_2 \cdot 2H_20$). It contains no antimicrobial agents.

Approximate pH 5.0 (4.0 to 6.5).



D-Glucopyranose monohydrate

Dextrose is derived from corn.

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 (≤ 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.

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

Hypersensitivity/infusion reactions have been reported with Lactated Ringer's and 5% Dextrose Injection, USP. Stop the infusion 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 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.

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.

Administer Lactated Ringer's and 5% Dextrose Injection, USP with particular caution 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.

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

Administer Lactated Ringer's and 5% Dextrose Injection, USP with particular caution to patients with severe renal impairment, hypervolemia, overhydration, or conditions that may cause sodium and/or potassium retention, fluid overload, or edema.

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.

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 is 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**.

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.

Drug Interactions

Ceftriaxone – see **CONTRAINDICATIONS**

Caution must be exercised 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

There are no adequate and well controlled studies with Lactated Ringer's and 5% Dextrose Injection, USP in pregnant women and animal reproduction studies have not

been conducted with this drug. Therefore, it is not known whether Lactated Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman. Lactated Ringer's and 5% Dextrose Injection, 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 Lactated Ringer's and 5% Dextrose Injection, 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 Lactated Ringer's and 5% Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use

The use of Lactated Ringer's and 5% Dextrose Injection, 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 infections, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

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 other drug therapy.

ADVERSE REACTIONS

Post-Marketing Adverse Reactions

The following adverse reactions have been reported in the post-marketing experience during the use of Lactated Ringer's and 5% Dextrose Injection, USP:

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.

Also reported are infusion site reactions, including infusion site pruritus, infusion site erythema, infusion site anesthesia (numbness).

Other adverse reactions reported with Lactated Ringer's Injection without Dextrose and Sodium Lactate Injection are: decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, laryngeal edema, flushing, throat irritation, paresthesias, hypoesthesia oral, dysgeusia, anxiety, headache, and sneezing, hyperkalemia, hypervolemia and other infusion site reactions, such as infection at the site of injection, phlebitis, extravasation, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pain, infusion site burning.

OVERDOSAGE

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, 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 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. Discard any unused portion.

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

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. See **PRECAUTIONS, Pediatric Use**.

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.

When introducing additives 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. 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. After addition, check for possible color changes 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 should not be used.

HOW SUPPLIED

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

Code	Size	NDC
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. 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.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Printed in USA

07-19-73-100
Rev. December 2017

Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP

in Plastic Container

VIAFLEX Plus Container

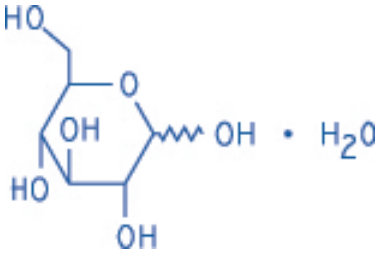
DESCRIPTION

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 mEq Potassium added	Size (mL)	Composition (g/L)					*Osmolarity (mOsmol/L) (calc.)
		**Dextrose Hydrous, USP	Sodium Chloride, USP (NaCl)	Sodium Lactate, ($C_3H_5NaO_3$)	Potassium Chloride, USP (KCl)	Calcium Chloride, USP ($CaCl_2 \bullet 2H_2O$)	
20 mEq	1000	50	6	3.1	1.79	0.2	565

* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
** The chemical structure for Dextrose Hydrous, USP is shown below:



D-Glucose monohydrate

Dextrose is derived from corn.

Table 2.

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

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

Hypersensitivity/infusion reactions have been reported with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP. Stop the infusion 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 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.

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.

Administer Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP with particular caution 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.

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

Administer Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP with particular caution 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

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.

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.

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

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). 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.

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 alkalinizing 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

There are no adequate and well-controlled studies with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman. Potassium Chloride in Lactated Ringer's

and 5% Dextrose Injection, 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 Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, 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 Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use

The use of Lactated Ringer's and 5% Dextrose Injection, 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 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 has been associated with intraventricular hemorrhage, late onset bacterial and fungal infections, retinopathy of prematurity, necrotizing entercolitis, bronchopulmary dysplasia, prolonged length of hospital stay, and death.

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 other drug therapy.

ADVERSE REACTIONS

Post-Marketing Adverse Reactions

The following adverse reactions have been reported in the post-marketing experience during the use of Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP:

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

Also reported are: infusion site reactions, including infusion site pruritus, infusion site erythema, infusion site anesthesia (numbness).

Other adverse reactions reported with Lactated Ringer's without Dextrose and Sodium Lactate Injection are:

- decreased heart rate, tachycardia, blood pressure decreased, respiratory distress, flushing, throat irritation, paresthesia, hypoesthesia oral, dysgeusia, anxiety and headache, hyperkalemia, hypervolemia and other infusion site reactions, such as infection at the site of injection, phlebitis, extravasation, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pain, infusion site burning.

OVERDOSAGE

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. Discard any unused portion.

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

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. See **PRECAUTIONS, Pediatric Use**.

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.

When introducing additives 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. 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. After addition, check for possible color changes 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 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

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. 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 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

07-19-73-101
Rev. December 2017