

LACELLATE SOLUTION - 1000- sodium chloride, potassium chloride, sodium lactate and calcium chloride injection, solution
IT3 Medical LLC

Lacellate Solution - 1000

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 ₃ H ₅ NaO ₃)	Potassium Chloride, USP, (KCl)	Calcium Chloride, USP (CaCl ₂ ·2H ₂ O)			Sodium	Potassium	Calcium	Chloride	Lactate	
Lactated Ringer’s Injection, USP	250 500 1000	6	3.1	0.3	0.2	273	6.5 (6.0 to 7.5)	130	4	2.7	109	28	9

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 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 (≤ 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 other 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

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
2B2324	1000	70529-027-01

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

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

For Information on Risk of Air Embolism – see PRECAUTIONS

To Open

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

Preparation for Administration

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

To Add Medication

To add medication before solution administration

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

To add medication during solution administration

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

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Assembled and Distributed by IT3 Medical, LLC 190 E Stacy Road; STE 306-298, Allen, TX 75002-8734

For questions or comments: info@IT3-Medical.com, www.IT3-Medical.com

Packaging



Lacellate Solution - 1000 Injection System

Contents:

- 1 - 1000mL Lactated Ringer's
Injection USP

 Single use only	 Caution, consult accompanying documents	 Consult instructions for use	 20°C 68°F Temperature limitations	 25°C 77°F Storage: Store in a cool dry place at 25°C (77°F). Excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.
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Lot/Expiration >

Lot : 111617
Exp : 8-1-18

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70529-027
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32Z N48698)	SODIUM CHLORIDE	600 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	310 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	30 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6Z B)	CALCIUM CHLORIDE	20 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70529-027-01	1 in 1 PACKAGE	03/01/2017	
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016682	03/01/2017	

Labeler - IT3 Medical LLC (079971231)

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IT3 Medical LLC