DEXTROSE IN LACTATED RINGERS- dextrose, sodium chloride, sodium lactate, potassium chloride, and calcium chloride injection, solution
B. Braun Medical Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LACTATED RINGER'S AND DEXTROSE (5%) INJECTION safely and effectively. See full prescribing information for LACTATED RINGER'S AND DEXTROSE (5%) INJECTION.

LACTATED RINGER'S AND DEXTROSE injection, for intravenous use Initial U.S. Approval: 1971

RECENT MAJOR CHANGES

Dosage and Administration (2.1, 2.2, 2.3, 2.4) 10/2025
Contraindications (4) 10/2025
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11) 10/2025

INDICATIONS AND USAGE

Lactated Ringer's and Dextrose (5%) Injection is indicated for use as a source of water, electrolytes, and calories or as an alkalinizing agent in adults and pediatric patients. (1)

DOSAGE AND ADMINISTRATION

- The recommended dosage and duration are based on the patient's age, weight, clinical condition, and concomitant therapy. (2.1)
- To reduce the risk of air embolism, adhere to the preparation instructions. (2.2, 5.2)
- Lactated Ringer's and Dextrose (5%) Injection is for intravenous use (2.3)
- Use a peripheral vein to administer if the final dextrose concentration is 5% or less and the osmolarity is less than 900 mOsm/L. (2.3)
- Consider using a central vein to administer hypertonic solutions with osmolarity of 900 mOsm/L or more to avoid venous irritation, including phlebitis. (2.3)
- Do not administer Lactated Ringer's and Dextrose (5%) Injection simultaneously with ceftriaxone in neonates (28 days of age or younger) due to serious risks. (2.4)
- See full prescribing information for information dosage considerations, preparation, administration, and drug incompatibilities. (2)

DOSAGE FORMS AND STRENGTHS

Injection: Lactated Ringer's and Dextrose (5%) Injection, USP packaged in single-dose EXCEL® containers: 500 mL and 1,000 mL (3)

CONTRAINDICATIONS

- Concomitant treatment with ceftriaxone in neonates (28 days of age or younger). (4)
- Patients with known hypersensitivity to sodium lactate. (4)

WARNINGS AND PRECAUTIONS

- Serious Risks with Inappropriate Use with Ceftriaxone: Deaths have occurred in neonates (28 days of age or younger) who received concomitant intravenous calcium-containing solutions with ceftriaxone. In patients older than 28 days, ceftriaxone and Lactated Ringer's and Dextrose (5%) Injection may be administered sequentially if the infusion lines are thoroughly flushed between infusions. (4, 5.1, 8.4)
- Air Embolism: Use a non-vented infusion set or close the vent on a vented set and use a dedicated line without any connections. Pressure infusion is **not** recommended to increase flow rates, but if necessary, remove all air from the bag prior to initiating infusion. (5.2)
- Hypersensitivity Reactions: Stop the Lactated Ringer's and Dextrose (5%) Injection infusion immediately if signs or symptoms of a hypersensitivity reaction develop. (5.3)
- Potassium Imbalances, Hyponatremia, Neonatal Hypoglycemia, Hyperglycemic and Hyperosmolar Hyperglycemic State Control, Hypercalcemia, Fluid Overload, Acid-Base Imbalances, Interference with Interpretation of Serum Lactate Levels in Patients with Severe Metabolic Acidosis: See Full Prescribing Information for risk management recommendations. (5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11)

ADVERSE REACTIONS

Common adverse reactions include infusion site reactions and symptoms of hypersensitivity reactions (e.g., pruritus, dyspnea, urticaria, rash, cough). (6)
To report SUSPECTED ADVERSE REACTIONS, contact B. Braun Medical Inc. at 1-833-425-1464 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Drugs that Affect Electrolyte and/or Fluid Balance: Avoid concomitant use. If concomitant use cannot be avoided, closely monitor electrolyte concentrations and fluid balance. (7.1)
- Lithium: Avoid concomitant use. If concomitant use is unavoidable monitor serum lithium concentrations more frequently. (7.2)
- Digoxin: Consider reducing the volume or rate of Lactated Ringer's and Dextrose (5%) Injection due to the increased risk of digoxin toxicity with calcium-containing solutions. (7.3)
- Drugs with pH-Dependent Renal Elimination: Renal clearance of acidic drugs may be increased. In contrast, renal clearance of alkaline drugs may be decreased. (7.4)

USE IN SPECIFIC POPULATIONS

- Closely monitor plasma electrolyte concentrations in young pediatric patients with immature kidney function. (8.4).
- Neonates are at increased risk of developing hypo- or hyperglycemia. Closely monitor to ensure adequate glycemic control. (8.4)
- Geriatric patients are more likely to have decreased renal function. Consider monitoring renal function and starting the infusion at the low end of the dosing range. (8.5)
- Avoid in patients with severe renal impairment. (8.6)
- Patients with severe hepatic impairment may have impaired lactate metabolism. Closely monitor serum lactate levels and acid-base status. (8.7)

Revised: 10/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Lactated Ringer's and Dextrose (5%) Injection is indicated for use as a source of water, electrolytes, and calories or as an alkalinizing agent in adults and pediatric patients.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage Considerations

The recommended dosage and duration of Lactated Ringer's and Dextrose (5%) Injection is based on the patient's age, weight, clinical condition, and concomitant therapy. Evaluate the patient's clinical status and monitor changes in blood glucose and electrolyte concentrations especially during prolonged use of Lactated Ringer's and Dextrose (5%) Injection to optimize clinical status.

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

2.2 Important Preparation Instructions

Visually inspect the Lactated Ringer's and Dextrose (5%) Injection solution for particulate matter and discoloration. Do not administer Lactated Ringer's and Dextrose (5%) Injection unless the solution is clear and the container seals are intact.

If additives are determined to be compatible with Lactated Ringer's and Dextrose (5%) Injection then using aseptic technique, mix thoroughly; do not store solutions containing additives. After mixing, do not use if there is discoloration or formation of precipitates.

To reduce the risk of air embolism, adhere to the following Lactated Ringer's and Dextrose (5%) Injection preparation instructions *[see Warnings and Precautions (5.2)]*:

- Use a non-vented infusion set or close the vent on a vented set.
- Use a dedicated line without any connections (do not connect flexible containers in series).
- The use of pressure infusion is **not** recommended as a method to increase flow rates. However, if pressure infusion is required, ensure that any air within the bag is fully evacuated prior to initiation of infusion.
- If using a pumping device to administer Lactated Ringer's and Dextrose (5%) Injection, turn off the pump before the container is empty.

Preparation Instructions
1. Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.
2. Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.
3. Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter. Any container which is suspect should not be used.
4. If supplemental medication is desired, follow directions below *[see Dosage and Administration (2.3)]*.

Preparation for Administration
1. Remove plastic protector from sterile set port at bottom of container.
2. Attach administration set according to its accompanying directions.

2.3 Important Administration Instructions

Lactated Ringer's and Dextrose (5%) Injection is for intravenous use.

- Use a peripheral vein to administer Lactated Ringer's and Dextrose (5%) Injection if the final dextrose concentration is 5% or less, and the osmolarity is less than 900 mOsm/L.
- Consider using a central vein to administer hypertonic solutions with osmolarity of 900 mOsm/L or more to avoid venous irritation *[see Warnings and Precautions (5.3)]*.
- It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use immediately after opening the container. Discard the unused portion.

Some additives may be incompatible *[see Dosage and Administration (2.4)]*.

To Add Medication Before Solution Administration
1. Prepare medication site.
2. Using syringe with 18-22 gauge needle, puncture medication port and inner diaphragm and inject.
3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.

To Add Medication During Solution Administration
1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18-22 gauge needle of appropriate length (at least 5/8 inch), puncture resealable medication port and inner diaphragm and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping and 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.

2.4 Drug Incompatibilities

Do not administer Lactated Ringer's and Dextrose (5%) Injection simultaneously with ceftriaxone in neonates (28 days of age or younger) due to serious risks *[see Contraindications (4) and Warnings and Precautions (5.1)]*. However, in patients older than 28 days, ceftriaxone and Lactated Ringer's and Dextrose (5%) Injection may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid *[see Warnings and Precautions (5.1)].*

Do not administer Lactated Ringer's and Dextrose (5%) Injection simultaneously with citrate anticoagulated/preserved blood through the same administration set because of the likelihood of coagulation precipitated by the calcium content of Lactated Ringer's and Dextrose (5%) Injection.

3 DOSAGE FORMS AND STRENGTHS

Injection: Lactated Ringer's and Dextrose (5%) Injection, USP as a clear, sterile, and nonpyrogenic solution packaged in single-dose EXCEL® containers: 500 mL and 1,000 mL.

4 CONTRAINDICATIONS

Lactated Ringer's and Dextrose (5%) Injection is contraindicated in:

- Neonates (28 days of age or younger) who are receiving concomitant treatment with ceftriaxone, even if separate infusion lines are used, due to the risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream *[see Warnings and Precautions (5.1) and Specific Populations (8.4)].*
- Patients with known hypersensitivity to any components of Lactated Ringer's and Dextrose (5%) Injection *[see Warnings and Precautions (5.3)].*
- Patients with clinically significant hyperglycemia *[see Warnings and Precautions (5.7)].*

5 WARNINGS AND PRECAUTIONS

5.1 Serious Risk with Concomitant Use with Ceftriaxone

Precipitation of ceftriaxone-calcium can occur when ceftriaxone is mixed with calcium-containing solutions, such as Lactated Ringer's and Dextrose (5%) Injection, in the same intravenous administration line. Deaths have occurred in neonates (28 days of age or younger) who received concomitant intravenous calcium-containing solutions with ceftriaxone resulting from calcium-ceftriaxone precipitates in the lungs and kidneys, even when separate infusion lines were used.

Lactated Ringer's and Dextrose (5%) Injection is contraindicated in neonates who receive ceftriaxone *[see Contraindications (4), Use in Specific Populations (8.4)]*. However, in patients older than 28 days, ceftriaxone and Lactated Ringer's and Dextrose (5%) Injection may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid.

5.2 Air Embolism

Cases of air embolism have been reported with pressurized administration of intravenous fluids. Air embolism may result in stroke, organ ischemia and/or infarction, and death.

Use a non-vented infusion set or close the vent on a vented set and use a dedicated line without any connections.

If administration is controlled by a pumping device, care must be taken to discontinue the pumping action before the container is empty.

Pressure infusion is **not** recommended to increase flow rates, but if necessary, ensure all air is removed from the bag before infusion.

Refrain from applying excessive pressure (>300mmHg) causing distortion to the container such as wringing or twisting. Such handling could result in breakage of the container *[see Dosage and Administration (2.2)]*.

5.3 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with Lactated Ringer's and Dextrose (5%) Injection. Stop the Lactated Ringer's and Dextrose (5%) Injection infusion immediately and treat patient accordingly if signs or symptoms of a hypersensitivity reaction develop. Initiate appropriate treatment as clinically indicated.

5.4 Potassium Imbalances

Hyperkalemia

Potassium-containing solutions, including Lactated Ringer's and Dextrose (5%) Injection, may increase the risk of hyperkalemia. This risk is increased in patients predisposed to hyperkalemia including those with severe renal impairment, acute dehydration, extensive tissue injury or burns, heart failure, or in those using concomitant drugs that are associated with hyperkalemia.

Avoid use of Lactated Ringer's and Dextrose (5%) Injection in patients with, or at increased risk for, hyperkalemia. If use cannot be avoided in these patients, closely monitor serum potassium concentrations.

Hypokalemia

The potassium concentration in Lactated Ringer's and Dextrose (5%) Injection is similar to the concentration in plasma. It is insufficient to normalize the serum potassium in patients with severe hypokalemia.

5.5 Hyponatremia

Lactated Ringer's and Dextrose (5%) Injection may cause hyponatremia. Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy and vomiting. The risk of hospital-acquired hyponatremia is increased in younger pediatric patients, geriatric patients, patients treated with diuretics, and patients with cardiac or pulmonary failure or with the syndrome of inappropriate antidiuretic hormone (SIADH) (e.g., postoperative patients, patients concomitantly treated with arginine vasopressin analogs, or certain antiepileptic, psychotropic, or cytotoxic drugs) *[see Drug Interactions (7.1), Use in Specific Populations (8.4)]*.

Avoid Lactated Ringer's and Dextrose (5%) Injection in patients with or at risk for hyponatremia. If use cannot be avoided in these patients, closely monitor serum sodium concentrations.

Rapid correction of hyponatremia may result in serious neurologic complications such as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and neurologic status.

5.6 Neonatal Hypoglycemia

Neonates, especially preterm neonates with low birth weight, are at increased risk of developing hypoglycemia. Closely monitor blood glucose concentration during treatment with intravenous dextrose solutions to ensure adequate glycemic control in order to avoid potential long-term adverse effects.

5.7 Hyperglycemia and Hyperosmolar Hyperglycemic State

Administration of solutions containing dextrose and lactate in patients with impaired glucose tolerance including those with diabetes mellitus may worsen hyperglycemia. Hyperglycemia is associated with an increase in serum osmolality, which can result in hypovolemia and electrolyte imbalances due to osmotic diuresis.

Patients with underlying central nervous system disease or renal impairment who receive dextrose infusions may be at greater risk of developing hyperosmolar hyperglycemic state.

While using Lactated Ringer's and Dextrose (5%) Injection, closely monitor blood glucose concentrations and treat hyperglycemia to maintain glucose concentrations within normal limits. Anti-diabetic drugs may need to be started or dosages of these drugs may need to be increased to maintain optimal blood glucose concentrations.

5.8 Hypercalcemia

Lactated Ringer's and Dextrose (5%) Injection contains calcium salts and may cause hypercalcemia. Avoid administration of Lactated Ringer's and Dextrose (5%) Injection in patients with hypercalcemia, those with calcium-containing renal calculi or history of such calculi, or those with conditions predisposing to hypercalcemia or treated with concomitant thiazide diuretics or vitamin D.

5.9 Fluid Overload

Depending on the administered volume and the infusion rate, administration of Lactated Ringer's and Dextrose (5%) Injection can cause fluid overload, including pulmonary edema.

Avoid Lactated Ringer's and Dextrose (5%) Injection in patients at risk for fluid and/or solute overload including patients with severe renal impairment. If use cannot be avoided in these patients, monitor fluid balance, electrolyte concentrations and acid base balance, especially during prolonged use.

5.10 Acid/Base Imbalances

Because lactate is metabolized to bicarbonate, administration of Lactated Ringer's and Dextrose (5%) Injection may result in, or worsen, metabolic alkalosis. Closely monitor the acid-base balance in patients with, or at risk of, alkalosis.

In patients with severe hepatic impairment, decreased lactate metabolism may result in worsening anion gap metabolic acidosis. Avoid Lactated Ringer's and Dextrose (5%) Injection in patients with severe hepatic impairment. If use cannot be avoided in these patients, closely monitor serum bicarbonate levels.

5.11 Interference of Lactated Ringer's and Dextrose (5%) Injection with Interpretation of Serum Lactate Levels in Patients with Severe Metabolic Acidosis

Administration of Lactated Ringer's and Dextrose (5%) Injection may result in interference with the interpretation of serum lactate levels in patients with severe metabolic acidosis. *[see Drug Interactions (7.5)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Serious Risk with Concomitant Use with Ceftriaxone *[see Warnings and Precautions (5.1)]*
- Air Embolism *[see Warnings and Precautions (5.2)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.3)]*
- Potassium Imbalances *[see Warnings and Precautions (5.4)]*
- Hyponatremia *[see Warnings and Precautions (5.5)]*
- Neonatal Hypoglycemia *[see Warnings and Precautions (5.6)]*
- Hyperglycemia and Hyperosmolar Hyperglycemic State *[see Warnings and Precautions (5.7)]*
- Hypercalcemia *[see Warnings and Precautions (5.8)]*
- Fluid Overload *[see Warnings and Precautions (5.9)]*
- Acid/Base Imbalances *[see Warnings and Precautions (5.10)]*

The following adverse reactions have been identified during post approval use of Lactated Ringer's Products. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

General Disorders and Administration Site Conditions:
Phlebitis, extravasation, infusion site inflammation, infusion site swelling, infusion site rash, infusion site pruritus, infusion site erythema, infusion site pain, infusion site burning, and infusion site hypoaesthesia.

Hypersensitivity Reactions and Infusion Reactions:
Angioedema, chest pain/discomfort, bradycardia or tachycardia, hypotension, respiratory distress, bronchospasm, dyspnea, cough, urticaria, rash, pruritus, erythema, flushing, throat irritation, paresthesia, oral hypoesthesia, dysgeusia, nausea, anxiety, pyrexia, and headache, laryngeal edema, sneezing, and injection site infection.

Metabolism and Nutrition Disorders:
Hyperkalemia, hyponatremia, and hypervolemia.

Nervous System Disorders:
Hyponatremic encephalopathy.

7 DRUG INTERACTIONS

7.1 Drugs that Affect Electrolyte and/or Fluid Balance

Hyperkalemia

Administration of Lactated Ringer's and Dextrose (5%) Injection to patients concomitantly treated or recently treated with drugs that are associated with hyperkalemia increases the risk of severe and potentially fatal hyperkalemia, especially in the presence of other hyperkalemia risk factors. Avoid use of Lactated Ringer's and Dextrose (5%) Injection in patients receiving drugs that are associated with hyperkalemia (e.g., potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, or calcineurin inhibitors). If concomitant use cannot be avoided, closely monitor serum potassium concentrations during concomitant use *[see Warnings and Precautions (5.4)]*.

Hyponatremia

Administration of Lactated Ringer's and Dextrose (5%) Injection to patients treated concomitantly with drugs associated with hyponatremia may increase the risk of developing hyponatremia. These drugs include diuretics and those that cause SIADH (e.g., arginine vasopressin analogs, certain antiepileptic, psychotropic, or cytotoxic drugs). Avoid use of Lactated Ringer's and Dextrose (5%) Injection in patients receiving such drugs. If use cannot be avoided, closely monitor serum sodium concentrations during concomitant use *[see Warnings and Precautions (5.5)]*.

Hypercalcemia

Avoid the use of Lactated Ringer's and Dextrose (5%) Injection in patients treated with thiazide diuretics or vitamin D because these drugs can increase the risk of hypercalcemia. If use cannot be avoided, closely monitor serum calcium concentrations during concomitant use *[see Warnings and Precautions (5.8)]*.

Hypernatremia and Fluid Retention

Administration of Lactated Ringer's and Dextrose (5%) Injection to patients treated concomitantly with drugs associated with sodium and fluid retention (e.g., corticosteroids or corticotropin) may increase the risk of hypernatremia and volume overload. Avoid use of Lactated Ringer's and Dextrose (5%) Injection in patients receiving such drugs. If use cannot be avoided, closely monitor serum electrolytes, fluid balance, and acid-base balance during concomitant use.

7.2 Lithium

Renal sodium and lithium clearance may be increased during concomitant use of Lactated Ringer's and Dextrose (5%) Injection and lithium and may result in decreased lithium concentrations. Avoid use of Lactated Ringer's and Dextrose (5%) Injection in

patients receiving lithium. If use cannot be avoided, increase the frequency of monitoring of serum lithium concentrations during concomitant use.

7.3 Digoxin

Administration of calcium via use of Lactated Ringer's and Dextrose (5%) Injection may increase digoxin's effects and lead to digoxin toxicity including serious or fatal cardiac arrhythmias. In digoxin-treated patients, consider reducing the volume and/or rate of Lactated Ringer's and Dextrose (5%) Injection administration.

7.4 Drugs with pH-Dependent Renal Elimination

Due to the alkalinizing action of lactate (formation of bicarbonate), Lactated Ringer's and Dextrose (5%) Injection may interfere with the elimination of drugs with pH-dependent renal elimination. Renal clearance of alkaline drugs may be decreased. In contrast, renal clearance of acidic drugs may be increased.

7.5 Interference of Lactated Ringer's and Dextrose (5%) Injection with Interpretation of Serum Lactate Levels in Patients with Severe Metabolic Acidosis

Because administration of Lactated Ringer's and Dextrose (5%) Injection may interfere with the interpretation of serum lactate levels in patients with severe metabolic acidosis; assessment of the patient's clinical status should not solely rely on the measurement of serum lactate.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Lactated Ringer's as a source of water and electrolytes has been used for decades during labor and delivery. Although there are no reports of use of Lactated Ringer's in other stages of pregnancy, exposure during pregnancy is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with this drug.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

Lactated Ringer's as a source of water and electrolytes and Dextrose Injection (5%) have been used for decades and is not expected to cause harm to a breastfed infant. There are no data on the presence of Lactated Ringer's and Dextrose (5%) Injection in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Lactated Ringer's and Dextrose (5%) Injection and any potential adverse effects on the breastfed infant from Lactated Ringer's and Dextrose (5%) Injection or from the underlying maternal condition.

8.4 Pediatric Use

Lactated Ringer's and Dextrose (5%) Injection is contraindicated in neonates (28 days of age or younger) who are receiving ceftriaxone due to reported deaths that occurred when neonates received ceftriaxone and intravenous calcium-containing solutions concomitantly *[see Warnings and Precautions (5.1)]*.

The safety and effectiveness of Lactated Ringer's Injection for use as a source of water, electrolytes, and calories or as an alkalinizing agent have been established in pediatric patients of all ages, including neonates.

Closely monitor plasma electrolyte concentrations in young pediatric patients with immature kidney function who may have decreased ability to maintain fluid and electrolyte balance *[see Warnings and Precautions (5.4, 5.5, 5.8, 5.9)]*. Administration of a lactate-containing intravenous solution, including Lactated Ringer's and Dextrose (5%) Injection to pediatric patients should account for liver and kidney maturation (the kidney function affects the biotransformation and renal excretion of lactate *[see Warnings and Precautions (5.9)]*. Pediatric patients are at increased risk for developing hyponatremic encephalopathy *[see Warnings and Precautions (5.5)]*.

Neonates, especially preterm neonates with low birth weight, are at increased risk of developing hypo- or hyperglycemia and therefore need close monitoring during treatment with intravenous glucose solutions including Lactated Ringer's and Dextrose (5%) Injection to ensure adequate glycemic control to avoid potential long-term adverse reactions *[see Warnings and Precautions (5.6, 5.7)]*. In very low birth weight neonates,

excessive or rapid administration of Lactated Ringer's and Dextrose (5%) Injection may result in increased serum osmolality and risk of intracranial hemorrhage.

8.5 Geriatric Use

Geriatric patients treated with Lactated Ringer's and Dextrose (5%) Injection are at increased risk of developing electrolyte imbalances. Lactated Ringer's and Dextrose (5%) Injection is substantially excreted by the kidney, and the risk of adverse reactions to Lactated Ringer's and Dextrose (5%) Injection may be greater in patients with renal impairment than in patients with normal renal function. Because geriatric patients are more likely to have decreased renal function, consider monitoring renal function in geriatric patients and consider starting the infusion at the low end of the dosing range.

8.6 Renal Impairment

Administration of Lactated Ringer's and Dextrose (5%) Injection to patients with or at risk of severe renal impairment, may result in hyperkalemia and/or fluid overload *[see Warnings and Precautions (5.4, 5.7, 5.9)]*. Avoid Lactated Ringer's and Dextrose (5%) Injection in patients with severe renal impairment. If use cannot be avoided in such patients, monitor for development of these adverse reactions.

8.7 Hepatic Impairment

In patients with severe hepatic impairment, lactate metabolism may be impaired and Lactated Ringer's and Dextrose (5%) Injection may not produce alkalinization. Closely monitor serum lactate levels and acid-base status in such patients.

10 OVERDOSAGE

Excessive administration of Lactated Ringer's and Dextrose (5%) Injection can cause:

- Hyperkalemia and hypernatremia, especially in patients with severe renal impairment.
- Fluid overload (which can lead to pulmonary and/or peripheral edema).
- Hyperglycemia, hyperosmolarity, and osmotic diuresis, dehydration, and electrolyte loss.
- Metabolic alkalosis with or without hypokalemia.
- Loss of bicarbonate with an acidifying effect
- Hypercalcemia

Overdose interventions include Lactated Ringer's and Dextrose (5%) Injection discontinuation, treatment of hyperkalemia, treatment of hyperglycemia, and close monitoring of fluid balance, electrolyte concentrations, and acid-base balance *[see Warnings and Precautions (5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10)].*

11 DESCRIPTION

Lactated Ringer's and Dextrose (5%) Injection USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single-dose container for intravenous administration.

Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1. Dextrose is derived from corn.

Table 1

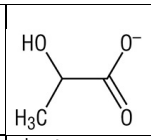
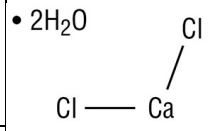
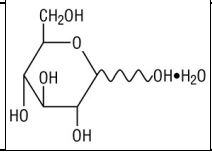
	Size (mL)	Composition (g/L)					Osmolarity* (mOsmol/L) (calc)	pH†	Ionic Concentration (mEq/L)				Lactate	Caloric Content (kcal/L)
		Dextrose, USP	Sodium Chloride, USP	Sodium Lactate	Potassium Chloride, USP	Calcium Chloride, USP			Sodium	Potassium	Calcium	Chloride		
Lactated Ringer's and Dextrose (5%) Injection, USP	500 1000	50	6	3.1	0.3	0.2	530	4.6 (4.0 to 6.0)	130	4	3	112	28	180

* Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.
† pH adjusted with Hydrochloric Acid NF.

The chemical name, structural formula, and molecular weight of the active ingredients are shown in Table 2.

Table 2

Ingredients	**Molecular Formula**	**Molecular Weight**
Sodium Chloride USP	$Na^+ Cl^-$	58.44

Sodium Lactate		112.06
Potassium Chloride USP	$K^+ Cl^-$	74.55
Calcium Chloride Dihydrate USP		147.02
Dextrose USP		198.17

Not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multilayered film developed for parenteral drugs. It contains no plasticizers and has minimal leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site *[see Dosage and Administration (2.3)].*

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Lactated Ringer's and Dextrose (5%) Injection is a source of water, electrolytes, and calories, and produces an alkalinizing effect.

- Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.
- Potassium, the principal cation of intracellular fluid, participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart.
- Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.
- Calcium, an important cation, provides the framework of bones and teeth in the form of calcium phosphate and calcium carbonate. In the ionized form, calcium is essential for the functional mechanism of the clotting of blood, normal cardiac function, and regulation of neuromuscular irritability.
- Sodium lactate provides sodium and lactate ions. The lactate anion is in equilibrium with pyruvate and has an alkalinizing effect resulting from simultaneous removal by the liver of lactate and hydrogen ions. The sodium ion combines with bicarbonate ion produced from carbon dioxide of the body and thus retains bicarbonate to combat metabolic acidosis (bicarbonate deficiency).
- Dextrose provides a source of calories. Dextrose may decrease losses of body protein and nitrogen, promotes glycogen deposition and decreases or prevents ketosis if sufficient doses are provided.

12.2 Pharmacodynamics

The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of Lactated Ringer's and Dextrose (5%) Injection have not been fully characterized.

12.3 Pharmacokinetics

Elimination

Metabolism/Excretion

Potassium: Normally about 80 to 90% of the potassium intake is excreted in the urine; the remainder is excreted in feces and to a smaller extent, in perspiration.

Sodium and Chloride: The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

Lactate: In the liver, lactate is metabolized to carbon dioxide and water by oxidative metabolism and consumption of hydrogen cations.

Dextrose: Dextrose injected parenterally undergoes oxidation to carbon dioxide and water.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, genetic toxicology, and animal fertility studies have not been conducted with Lactated Ringer's and Dextrose (5%) Injection.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Lactated Ringer's and Dextrose (5%) Injection USP is supplied sterile and nonpyrogenic in single-dose EXCEL® Containers. The 1000 mL containers are packaged 12 per case, the 500 mL containers are packaged 24 per case.

It is available in the following presentations:

NDC	REF	Size
0264-7751-00	L7510	1000 mL
0264-7751-10	L7511	500 mL

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.] Minimize exposure of Lactated Ringer's and Dextrose (5%) Injection to heat. Avoid excessive heat. Protect from freezing.

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Rx only

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y36-003-100 LD-380-7

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

5% Dextrose in
Lactated Ringer's
Injection
REF L7510
NDC 0264-7751-00

1000 mL
EXCEL® CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.6 g; Sodium Lactate 0.31 g; Potassium Chloride USP 0.03 g; Calcium Chloride•$2H_2O$ USP 0.02 g; Water for Injection USP qs

pH adjusted with HCl NF
pH: 4.6 (4.0-6.0); Calc. Osmolarity: 530 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na^+ 130; K^+ 4; Ca^{++} 3; Cl^- 112; Lactate 28

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS.

Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the

overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y94-003-220 LD-141-4

EXP
LOT

5% Dextrose in Lactated Ringer's Injection

REF L7510
NDC 0264-7751-00

1000 mL
EXCEL® CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.6 g; Sodium Lactate 0.31 g; Potassium Chloride USP 0.03 g; Calcium Chloride•$2H_2O$ USP 0.02 g; Water for Injection USP qs

pH adjusted with HCl NF

pH: 4.6 (4.0–6.0); Calc. Osmolarity: 530 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na^+ 130; K^+ 4; Ca^{++} 3; Cl^- 112; Lactate 28

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS. Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP. Rx only

7 OTHER

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BARCODE

BARCODE

Y94-003-220 LD-141-4

B|BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

EXP LOT

-0-
-1-
-2-
-3-
-4-
-5-
-6-
-7-
-8-
-9-

PRINCIPAL DISPLAY PANEL - 500 mL Container Label

5% Dextrose in
Lactated Ringer's Injection

REF L7511
NDC 0264-7751-10

500 mL
EXCEL® CONTAINER
Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.6 g; Sodium Lactate 0.31 g; Potassium Chloride USP 0.03 g; Calcium Chloride•$2H_2O$ USP 0.02 g; Water for Injection USP qs

pH adjusted with HCl NF
pH: 4.6 (4.0-6.0); Calc. Osmolarity: 530 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na^+ 130; K^+ 4; Ca^{++} 3; Cl^- 112; Lactate 28

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS.

Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

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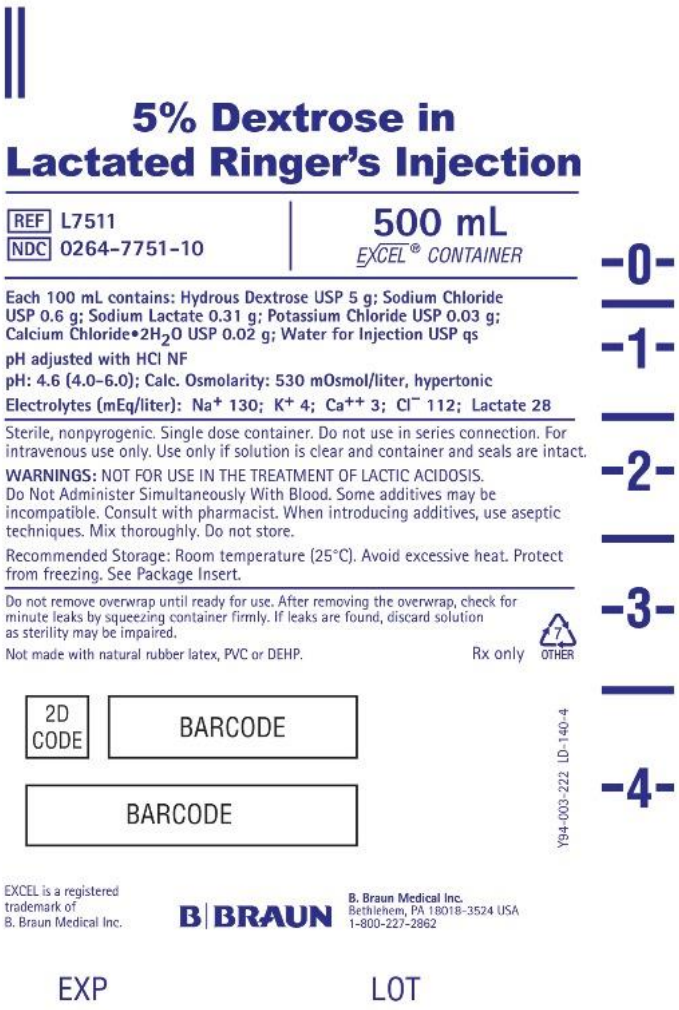
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

Y94-003-222
LD-140-4

EXP
LOT



DEXTROSE IN LACTATED RINGERS

dextrose, sodium chloride, sodium lactate, potassium chloride, and calcium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-7751
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.6 g in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	0.31 g in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	0.03 g in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	0.02 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-7751-00	12 in 1 CASE	02/24/1988	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264-7751-10	24 in 1 CASE	02/24/1988	
2		500 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019634	02/24/1988	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 11/2025

B. Braun Medical Inc.