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

Lactated Ringer's Injection USP

DESCRIPTION

Rx only

Each 100 mL of Lactated Ringer's Injection USP contains:
Sodium Chloride USP 0.6 g; Sodium Lactate 0.31 g
Potassium Chloride USP 0.03 g; Calcium Chloride Dihydrate USP 0.02 g
Water for Injection USP qs

pH may be adjusted with Hydrochloric Acid NF or Sodium Hydroxide NF
pH: 6.2 (6.0–7.5) Calculated Osmolarity: 274 mOsmol/liter

Concentration of Electrolytes (mEq/liter): Sodium 130; Potassium 4;
Calcium 3; Chloride 109; Lactate ($CH_3CH(OH)COO^-$) 28

Lactated Ringer's Injection USP is sterile, nonpyrogenic and contains no bacteriostatic or antimicrobial agents. This product is intended for intravenous administration in a single dose container.

The formulas of the active ingredients are:

Ingredients	Molecular Formula	Molecular Weight
Sodium Chloride USP	NaCl	58.44
Sodium Lactate	$CH_3CH(OH)COONa$	112.06
Potassium Chloride USP	KCl	74.55
Calcium Chloride Dihydrate USP	$CaCl_2 \cdot 2H_2O$	147.02

Not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. 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.

Addition of medication should be accomplished using complete aseptic technique.

The closure system has two ports; the one for the administration set has a tamper evident foil cover and the other is a medication addition site. Refer to the Directions for Use of the container.

CLINICAL PHARMACOLOGY

Lactated Ringer's Injection USP provides electrolytes and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient. This solution also contains lactate which produces a metabolic 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 is a racemic salt containing both the levo form, which is oxidized by the liver to bicarbonate, and the dextro form, which is converted to glycogen. Lactate is slowly metabolized to carbon dioxide and water, accepting one hydrogen ion and resulting in the formation of bicarbonate for the lactate consumed. These reactions depend on oxidative cellular activity.

INDICATIONS AND USAGE

This solution is indicated for use in adults and pediatric patients as a source of electrolytes and water for hydration.

CONTRAINDICATIONS

The use of Lactated Ringer’s Injection USP is contraindicated in neonates (28 days of age or younger) 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, Drug Interactions, Pediatric Use*].

This solution is contraindicated where the administration of sodium, potassium, calcium, lactate, or chloride could be clinically detrimental.

Lactate administration is contraindicated in severe metabolic acidosis or alkalosis, and in severe liver disease or anoxic states which affect lactate metabolism.

WARNINGS

Precipitation with Ceftriaxone

Precipitation of ceftriaxone-calcium can occur when ceftriaxone is mixed with calcium-containing solutions, such as Lactated Ringer’s Injection USP, in the same intravenous administration line. Do not administer ceftriaxone simultaneously with Lactated Ringer’s Injection USP via a Y-site.

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 Injection USP is contraindicated in neonates receiving ceftriaxone.

However, in patients other than neonates, ceftriaxone and Lactated Ringer's Injection USP may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid. [see *Contraindications, Warnings, Drug Interactions, Pediatric Use*].

Solutions containing lactate are not for use in the treatment of lactic acidosis.

Solutions containing lactate should be used with great care in patients with metabolic or respiratory alkalosis, and in those conditions in which there is an increased level or an impaired utilization of lactate, such as severe hepatic insufficiency.

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there is sodium retention with edema.

Solutions containing potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium ions retention is present.

In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention.

Solutions containing calcium ions should not be administered through the same administration set as blood because of the likelihood of coagulation.

PRECAUTIONS

General

This solution should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation.

Extraordinary electrolytes losses such as may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Additional essential electrolytes, minerals and vitamins should be supplied as needed.

Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients.

Care should be exercised in administering solutions containing sodium or potassium to patients with renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels.

Solutions containing calcium should be used with caution in the presence of cardiac disease, particularly when accompanied by renal disease. Parenteral calcium should be administered with extreme caution to patients receiving digitalis preparations.

Solutions containing lactate should be used with caution. Excess administration may result in metabolic alkalosis.

The conversion of lactate to bicarbonate is markedly delayed in the presence of tissue anoxia and reduced capacity of the liver to metabolize lactate. This may occur under conditions such as metabolic acidosis associated with circulatory insufficiency, extracorporeal circulation, hypothermia, glycogen storage disease, liver dysfunction, respiratory alkalosis, shock or cardiac decompensation.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

Do not use plastic container in series connection.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result. If administration is not controlled by a pumping device, 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.

This solution is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require tailoring of the electrolyte pattern, in this or an alternative solution.

Drug Interactions

Ceftriaxone

Precipitation of ceftriaxone-calcium can occur when ceftriaxone is mixed with calcium-containing solutions, such as Lactated Ringer’s Injection USP, in the same intravenous administration line. Do not administer ceftriaxone simultaneously with Lactated Ringer’s Injection USP via a Y-site. However, in patients other than neonates, ceftriaxone and Lactated Ringer’s Injection USP may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid [see *Warnings, Dosage and Administration*].

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 [see *Contraindications, Warnings, Pediatric Use, Dosage and Administration*].

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Lactated Ringer's Injection USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

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.

Labor and Delivery

As reported in the literature, Lactated Ringer's Injection USP has been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

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 woman.

Pediatric Use

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 Injection USP is contraindicated in neonates receiving ceftriaxone [see *Contraindications, Warnings, Drug Interactions*].

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.

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.

ADVERSE REACTIONS

Allergic reactions or anaphylactoid symptoms such as localized or generalized urticaria and pruritus; periorbital, facial, and/or laryngeal edema; coughing, sneezing, and/or difficulty with breathing have been reported during administration of Lactated Ringer's Injection USP. The reporting frequency of these signs and symptoms is higher in women during pregnancy.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential.

Hypernatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

Abnormally high plasma levels of calcium can result in depression, amnesia, headaches, drowsiness, disorientation, syncope, hallucinations, hypotonia of both skeletal and smooth muscles, dysphagia, arrhythmias and coma. Calcium deficits can result in neuromuscular hyperexcitability, including cramps and convulsions.

Although the metabolism of lactate to bicarbonate is a relatively slow process, aggressive administration of sodium lactate may result in metabolic alkalosis. Careful monitoring of blood acid-base balance is essential during the administration of sodium lactate.

The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of a fluid or solute overload during parenteral therapy, reevaluate the

patient's condition and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:
1. Dextrose Injection USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

DOSAGE AND ADMINISTRATION

This solution is for intravenous use only.

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

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

The presence of calcium ions in this solution should be considered when phosphate is present in additive solutions, in order to avoid precipitation.

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

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

Ceftriaxone must not be administered simultaneously with calcium-containing intravenous solutions such as Lactated Ringer’s Injection USP via a Y-site. However, in patients other than neonates, ceftriaxone and Lactated Ringer’s Injection USP may be administered sequentially if the infusion lines are thoroughly flushed between infusions with a compatible fluid [see *Contraindications, Warnings, Drug Interactions, Pediatric Use*].

HOW SUPPLIED

Lactated Ringer's Injection USP is supplied sterile and nonpyrogenic in EXCEL® Plus Containers. The 1000 mL containers are packaged 12 per case, and 500 mL containers are packaged 24 per case.

NDC	REF	Size
Lactated Ringer's Injection USP		
0264-7500-00	Q7500	1000 mL

0264-7501-10 Q7501 500 mL

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.] Avoid excessive heat. Protect from freezing.

Revised: May 2023
EXCEL is a registered trademark of B. Braun Medical Inc.

Directions for Use of EXCEL® Plus Container

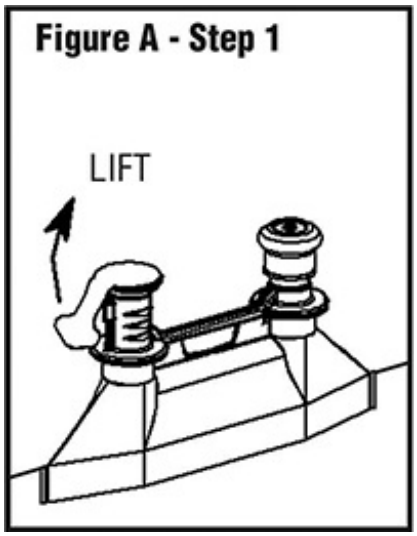
Caution: Do not use plastic container in series connection.

To Open

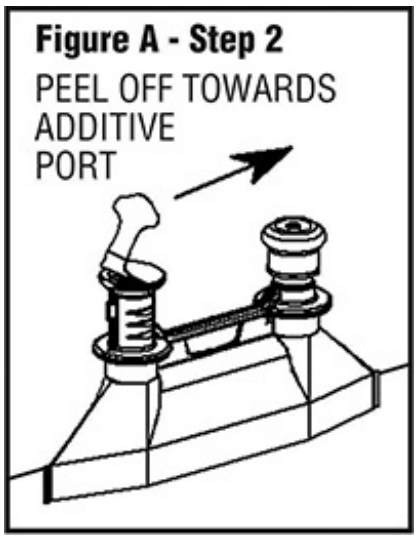
Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

NOTE: Before use, perform the following checks:
- Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.
- 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.
- Use only if solution is clear and container and seals are intact.

Preparation for Administration
1. Remove foil cover from sterile set port at bottom of container as shown in **Figure A, Steps 1 and 2**.



Step 1



Step 2

2. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Some additives may be incompatible.

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.

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Bethlehem, PA 18018-3524 USA
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Y36-003-076 LD-741-2

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

Lactated Ringer's

Injection USP

REF Q7500
NDC 0264-7500-00

1000 mL
EXCEL® PLUS CONTAINER

Each 100 mL contains: 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 may be adjusted with HCl NF or NaOH NF
pH: 6.2 (6.0-7.5); Calc. Osmolarity: 274 mOsmol/liter

Electrolytes (mEq/liter): Na^+ 130; K^+ 4; Ca^{++} 3;
Cl^- 109; Lactate 28

Sterile, nonpyrogenic. Single-dose container. Do not administer simultaneously with blood. 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. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

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.] Avoid excessive heat. Protect from freezing.
Dosage: See Prescribing Information.

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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Y94-003-498
LD-739-2

Lactated Ringer's Injection USP

REF Q7500
NDC 0264-7500-00

1000 mL
EXCEL® PLUS CONTAINER

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-1-

Each 100 mL contains: 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

-2-

pH may be adjusted with HCl NF or NaOH NF
pH: 6.2 (6.0-7.5); Calc. Osmolarity: 274 mOsmol/liter

-3-

Electrolytes (mEq/liter): Na^+ 130; K^+ 4;
Ca^{++} 3; Cl^- 109;
Lactate 28

2D CODE

-4-

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

-5-

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

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

-6-

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.] Avoid excessive heat. Protect from freezing.
Dosage: See Prescribing Information.

-7-

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.

-8-

Not made with natural rubber latex, PVC or DEHP.

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Rx only

7 OTHER

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Y94-003-498
LD-739-2

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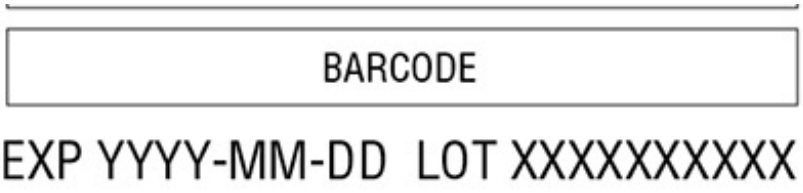
BARCODE



LR 1000 mL

PRINCIPAL DISPLAY PANEL - 500 mL Container Label

Lactated Ringer's
Injection USP

REF Q7501
NDC 0264-7501-10

500 mL
EXCEL® PLUS CONTAINER

Each 100 mL contains: 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 may be adjusted with HCl NF or NaOH NF
pH: 6.2 (6.0-7.5); Calc. Osmolarity: 274 mOsmol/liter

Electrolytes (mEq/liter): Na^+ 130; K^+ 4; Ca^{++} 3; Cl^- 109; Lactate 28

Sterile, nonpyrogenic. Single-dose container. Do not administer simultaneously with blood.
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. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

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.] Avoid excessive heat. Protect from freezing. Dosage: See Prescribing Information.

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.

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1-800-227-2862

Y94-003-497
LD-740-2

Lactated Ringer's Injection USP

REF Q7501
NDC 0264-7501-10

500 mL
EXCEL® PLUS CONTAINER

Each 100 mL contains: 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 may be adjusted with HCl NF or NaOH NF
pH: 6.2 (6.0–7.5); Calc. Osmolarity: 274 mOsmol/liter
Electrolytes (mEq/liter): Na^+ 130; K^+ 4; Ca^{++} 3; Cl^- 109; Lactate 28

2D CODE

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-1-

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

-2-

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

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

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.] Avoid excessive heat. Protect from freezing. Dosage: See Prescribing Information.

-3-

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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1-800-227-2862

BARCODE

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BARCODE

EXP YYYY-MM-DD LOT XXXXXXXXXX

Y94-003-497
LD-740-2

LR 500 mL

LACTATED RINGERS

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-7500
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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 CATION - UNII:LYR4M0NH37)	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:0264-7500-00	12 in 1 CASE	03/01/2023	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264-7500-10	24 in 1 CASE	03/01/2023	
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	NDA019632	03/01/2023	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 5/2023 B. Braun Medical Inc.