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

Lactated Ringer's Irrigation

Y36-002-965 LD-780-1

Package Insert

PIC™ (Plastic Irrigation Container)

FOR ALL GENERAL IRRIGATION, WASHING AND RINSING PURPOSES

Not For Injection By Usual Parenteral•Routes

Semi-rigid Irrigation Container

Isotonic Solution for Irrigation.

For Irrigation Only. Not for Injection.

Rx only

DESCRIPTION

Lactated Ringer's Irrigation is a sterile, nonpyrogenic, solution of electrolytes in water for injection intended only for sterile irrigation, washing and rinsing purposes. The composition is based on a modification of the injectable formula originally known as Hartmann's Solution.

Each 100 mL 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 adjusted with Hydrochloric Acid NF
pH: 6.75 (6.0–7.5) Calculated Osmolarity: 275 mOsmol/liter

Concentration of Electrolytes (mEq/liter): Sodium 130, Potassium 4, Calcium 3, Chloride 110, Lactate ($CH_3CH(OH)COO^-$) 28

The solution contains no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and is intended only for use as a single-dose or short procedure irrigation. When smaller volumes are required the unused portions should be discarded. Lactated Ringer's Irrigation may be classified as a sterile irrigant, wash, rinse and pharmaceutical vehicle.

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	$CaCl_2 \cdot 2H_2O$	147.01

The plastic container is a copolymer of ethylene and propylene formulated and developed for parenteral drugs. The copolymer contains no plasticizers and exhibits virtually no leachability. The plastic container is also virtually impermeable to vapor transmission and therefore, requires no overwrap to maintain the proper drug concentration. The safety of the plastic container has been confirmed by biological evaluation procedures. The material passes Class Vl testing as specified in the U.S. Pharmacopeia for Biological Tests — Plastic Containers. These tests have shown that the container is nontoxic and biologically inert.

Not made with natural rubber latex, PVC or DEHP.

CLINICAL PHARMACOLOGY

Lactated Ringer's Irrigation exerts a mechanical cleansing action for sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters and surgical drainage tubes, and for washing, rinsing or soaking surgical dressings, instruments and laboratory specimens. It also serves as a vehicle for drugs used for irrigation or other pharmaceutical preparations.

Lactated Ringer's Irrigation provides an isotonic irrigation with the same ionic constituents as Lactated Ringer's Injection, USP, a modification of Hartmann's Solution.Lactated Ringer's Irrigation is considered generally compatible with living tissues and organs.

Calcium chloride in water dissociates to provide calcium (Ca^{++}) and chloride (Cl^-) ions. They are normal constituents of the body fluids and are dependent on various physiologic mechanisms for maintenance of balance between intake and output. Approximately 80% of body calcium is excreted in the feces as insoluble salts; urinary excretion accounts for the remaining 20%.

Potassium chloride in water dissociates to provide potassium (K^+) and chloride (Cl^-) ions. Potassium is the chief cation of body cells (160 mEq/liter of intracellular water). It is found in low concentration in plasma and extracellular fluids (3.5 to 5 mEq/liter in a healthy adult). Potassium plays an important role in electrolyte balance.

Normally about 80 to 90% of the potassium intake is excreted in the urine; the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. 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.

Sodium lactate in water dissociates to provide sodium (Na^+) and lactate ($C_3H_5O^-_3$) ions. The lactate anion provides an alkalizing effect resulting from simultaneous removal by the liver of lactate and hydrogen ions. In the liver, the lactate is metabolized to glycogen

which is ultimately converted to carbon dioxide and water by oxidative metabolism.

The lactate anion acts as a source (alternate) of bicarbonate when normal production and utilization of lactic acid is not impaired as a result of disordered lactate metabolism. Since metabolic conversion is dependent on the integrity of cellular oxidative processes, lactate may be inadequate or ineffective as a source of bicarbonate in patients suffering from acidosis associated with shock or other disorders involving reduced perfusion of body tissues. When oxidative activity is intact, one to two hours time is required for metabolism of lactate.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

Lactated Ringer's Irrigation is indicated for all general irrigation, washing and rinsing purposes which permit use of a sterile, nonpyrogenic electrolyte solution.

CONTRAINDICATIONS

NOT FOR INJECTION BY USUAL PARENTERAL ROUTES.

An electrolyte solution should not be used for irrigation during electrosurgical procedures.

WARNINGS

FOR IRRIGATION ONLY. NOT FOR INJECTION.

Irrigating fluids have been demonstrated to enter the systemic circulation in relatively large volumes; thus this irrigation must be regarded as a systemic drug. Absorption of large amounts can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

Do not warm container over 150°F (66°C).

PRECAUTIONS

General

Do not use for irrigation that may result in absorption into the blood.

Caution should be observed when the solution is used for continuous irrigation or allowed to "dwell" inside body cavities because of possible absorption into the blood stream and the production of circulatory overload.

Aseptic technique is essential with the use of sterile solutions for irrigation of body cavities, wounds and urethral catheters or for wetting dressings that come in contact with body tissues.

When used as a "pour" irrigation, no part of the contents should be allowed to contact the surface below the outer protected thread area of the plastic irrigation container. When used for irrigation via irrigation equipment, the administration set should be attached promptly. Unused portions should be discarded and a fresh container of appropriate size used for the start-up of each cycle or repeat procedure. For repeated irrigations of urethral catheters, a separate container should be used for each patient

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

Pregnancy:

Teratogenic Effects

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

Pediatric Use

The safety and effectiveness of Lactated Ringer's Irrigation have not been established. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

ADVERSE REACTIONS

Possible adverse effects arising from the irrigation of body cavities, tissues, or indwelling catheters and tubes are usually avoidable when proper procedures are followed. Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities. Excessive volume or pressure during irrigation of closed cavities may cause undue distension or disruption of tissues. Accidental contamination from careless technique may transmit infection.

Should any adverse reaction occur, discontinue the irrigant, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See **WARNINGS, PRECAUTIONS** and **ADVERSE REACTIONS.**

DOSAGE AND ADMINISTRATION

The dose is dependent upon the capacity or surface area of the structure to be irrigated and the nature of the procedure. When used as a vehicle for other drugs, the manufacturer's recommendations should be followed.

Drug Interactions

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

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

HOW SUPPLIED

Lactated Ringer's Irrigation is supplied sterile and nonpyrogenic in PIC™ (Plastic Irrigation Container). The 1000 mL containers are packaged 16 per case.

NDC	Cat. No.	Size
Lactated Ringer's Irrigation		
0264-2203-00	R5410-01	1000 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. 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.] However, brief exposure up to 40°C does not adversely affect the product.

Do not warm above 150°F (66°C).

Revised: June 2023
PIC is a trademark of B. Braun Medical Inc.

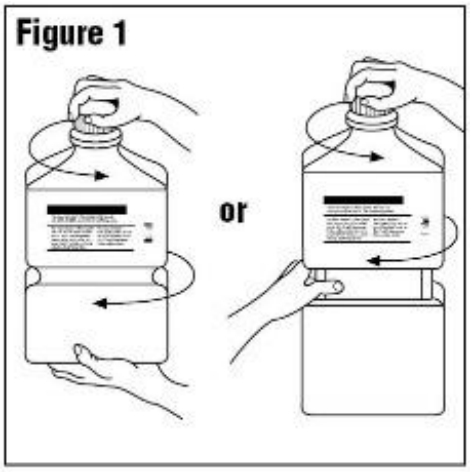
Directions for Use of PIC™ (Plastic Irrigation Container)

Not for injection.

Aseptic technique is required.

1. Caution – Before use, perform the following checks:
   (a) Read the label. Ensure solution is the one ordered and is within the expiration date.
   (b) Invert container and inspect the solution in good light for cloudiness, haze, or particulate matter; check the container for leakage or damage. Any container which is suspect should not be used.
   Use only if solution is clear and container and seal are intact.
   Single-dose container. Discard unused portion.
2. Outer Closure Removal – Grasp the container with one hand and turn the breakaway ring counterclockwise with the other hand until slight resistance is felt. Then, twisting

the container in the opposite direction, turn the breakaway ring **sharply** until the entire outer cap is loose and can be lifted off. (Figure 1)



3. Connect the administration set through the sterile set port according to set instructions (Figure 2) or remove screw cap and pour.

4. Do not warm above 150°F (66°C) to assure minimal bottle distortion. Keep bottles upright.

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

PRINCIPAL DISPLAY PANEL - 1000 mL Label

Lactated Ringer's Irrigation

Isotonic Solution for Irrigation

REF R5410-01 HK 22614
NDC 0264-2203-00

1000 mL
PIC™ Container

Rx only

Lot

Exp.

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 adjusted with HCl NF

pH: 6.75 (6.0 – 7.5)
Calc. Osmolarity: 275 mOsmol/liter

Electrolytes (mEq/liter): Na^+ 130
K^+ 4 Ca^{++} 3 Cl^- 110 Lactate 28

Sterile, nonpyrogenic. Single-dose container.

Discard unused portion.

Not for Injection. Use only if solution is clear and container and seal are intact.

Warning: Do not warm above 150°F (66°C).

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.] Avoid excessive heat. Protect from freezing.
Dosage: See Prescribing Information

Rx only

Not made with natural rubber latex, PVC or DEHP.

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Y37-002-528 LD-781-1

Lactated Ringer's Irrigation

LACTATED RINGERS

sodium chloride, sodium lactate, potassium chloride, and calcium chloride irrigant

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0264-2203
Route of Administration	IRRIGATION		

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) (SODIUM CATION - UNII:LYR4M0NH37, 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:0264-2203-00	16 in 1 CASE	12/27/1982	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264-2203-50	8 in 1 CASE	12/27/1982	12/31/2020
2		2000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
3	NDC:0264-2203-70	4 in 1 CASE	12/27/1982	04/30/2021
3		4000 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	NDA018681	12/27/1982	

Labeler - B. Braun Medical Inc. (002397347)

Revised: 9/2023 B. Braun Medical Inc.