

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

LACTATED RINGER'S IRRIGATION

FOR ALL GENERAL IRRIGATION, WASHING AND RINSING PURPOSES

Not For Injection By Usual Parenteral Routes

Flexible Irrigation Container

R_x 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 of Lactated Ringer's Irrigation contains: Sodium chloride 600 mg; sodium lactate, anhydrous 310 mg; potassium chloride 30 mg; calcium chloride, dihydrate 20 mg. The pH is 6.6 (6.0 — 7.5). The solution is isotonic (274 mOsmol/liter, calc.) and has the following electrolyte content (mEq/liter): Sodium (Na⁺) 130; potassium (K⁺) 4; calcium (Ca⁺⁺) 3; chloride (Cl⁻) 109 and lactate (CH₃CH(OH)COO⁻) 28. Contains sodium hydroxide and may contain hydrochloric acid for pH adjustment.

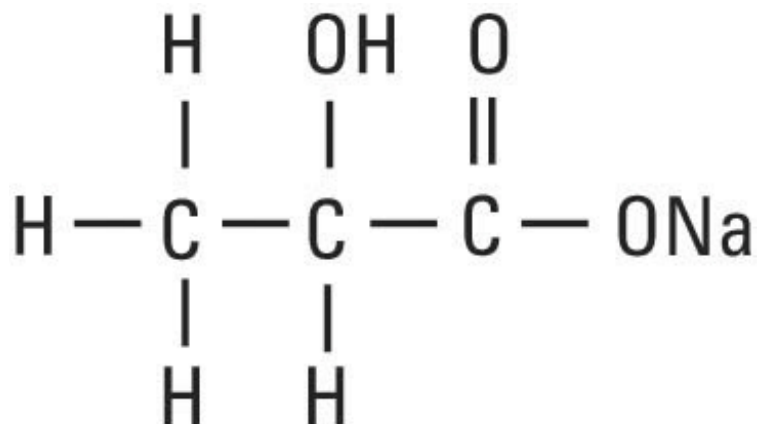
The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose or short procedure irrigation. When smaller volumes are required, the unused portion should be discarded. Lactated Ringer's Irrigation may be classified as a sterile irrigant, wash,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

Calcium Chloride, USP is chemically designated calcium chloride, dihydrate (CaCl₂ • 2H₂O), white fragments or granules freely soluble in water.

Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

Sodium Chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water.

Sodium Lactate, USP is chemically designated C₃H₅NaO₃, a 60% aqueous solution miscible in water. It has the following structural formula:



Water for Injection, USP is chemically designated H₂O.

The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions inside the plastic container also can leach out certain of its chemical components in very small amounts before the expiration period is attained. However, the safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers.

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 5.0 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 (C₃H₅O₃⁻) 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 (1.0 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 heat container over 66°C (150°F).

PRECAUTIONS

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.

The flexible container is designed for use with nonvented irrigation sets. 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.

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Pregnancy Category C.

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.

Tear at notch and along dotted line and remove container. 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.

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 in single-dose 3000 mL flexible irrigation containers (NDC No. 0409-7828-08 / 0990-7828-08).

ICU Medical is transitioning NDC codes from the "0409" to a "0990" labeler code. Both NDC codes are expected to be in the market for a period of time.

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.

Revised: June 2018

EN-4659

ICU Medical, Inc., Lake Forest, Illinois 60045 USA

PRINCIPAL DISPLAY PANEL - 3000 mL Bag Label

3000 mL

NDC 0990-7828-08

LACTATED
RINGER'S
IRRIGATION

EACH 100 mL CONTAINS SODIUM CHLORIDE 600 mg; SODIUM LACTATE, ANHYD. 310 mg; POTASSIUM CHLORIDE 30 mg; CALCIUM CHLORIDE, DIHYDRATE 20 mg IN WATER FOR INJECTION. CONTAINS NaOH AND MAY CONTAIN HCl FOR pH ADJUSTMENT.

ELECTROLYTES PER 1000 mL (NOT INCLUDING pH ADJUSTMENT): SODIUM 130 mEq; POTASSIUM 4 mEq; CALCIUM 3 mEq; CHLORIDE 109 mEq; LACTATE 28 mEq.

274 mOsmol/LITER (CALC). pH 6.6 (6.0 TO 7.5) STERILE NONPYROGENIC.

ISOTONIC SOLUTION FOR IRRIGATION.

CONTRAINDICATIONS: NOT FOR INJECTION.

USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED.

WARNINGS: DO NOT HEAT CONTAINER OVER 66°C (150°F). SINGLE-DOSE CONTAINER. CONTAINS NO BACTERIOSTAT. DISCARD UNUSED PORTION. USE ASEPTIC TECHNIQUE.

USUAL DOSAGE: SEE INSERT.

Rx only

3
V

CONTAINS DEHP

IM-4373

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

icumedical

3000 mL



NDC 0990-7828-08

LACTATED RINGER'S IRRIGATION

2750—

2500—

EACH **100 mL** CONTAINS SODIUM CHLORIDE 600 mg; SODIUM LACTATE, ANHYD. 310 mg; POTASSIUM CHLORIDE 30 mg; CALCIUM CHLORIDE, DIHYDRATE 20 mg IN WATER FOR INJECTION. CONTAINS NaOH AND MAY CONTAIN HCl FOR pH ADJUSTMENT.

2250—

2000—

ELECTROLYTES PER 1000 mL (NOT INCLUDING pH ADJUSTMENT): SODIUM 130 mEq; POTASSIUM 4 mEq; CALCIUM 3 mEq; CHLORIDE 109 mEq; LACTATE 28 mEq.

1750—

1500—

274 mOsmol/LITER (CALC). pH 6.6 (6.0 TO 7.5) STERILE NONPYROGENIC. ISOTONIC SOLUTION FOR IRRIGATION.

1250—

CONTRAINDICATIONS: NOT FOR INJECTION.

1000—

USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED.

WARNINGS: DO NOT HEAT CONTAINER OVER 66°C (150°F). SINGLE-DOSE CONTAINER. CONTAINS NO BACTERIOSTAT. DISCARD UNUSED PORTION. USE ASEPTIC TECHNIQUE

750—

PORTION. USE ASEPTIC TECHNIQUE.

USUAL DOSAGE: SEE INSERT.

Rx only



CONTAINS DEHP



500—

IM-4373

250—

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA



icumedical

PRINCIPAL DISPLAY PANEL - Pouch Label

TO OPEN TEAR AT NOTCH

2

HDPE

DO NOT REMOVE FROM 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. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.

98-4321-R14-3/98

TO OPEN TEAR AT NOTCH



HDPE

DO NOT REMOVE FROM 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. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.

98-4321-R14-3/98

LACTATED RINGERS

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-7828
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	600 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID, UNSPECIFIED FORM - UNII:33X04XA5AT)	SODIUM LACTATE	310 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	30 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	20 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-7828-08	4 in 1 CASE	07/01/2019	
1		1 in 1 POUCH		
1		3000 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	NDA019416	07/01/2019	

Labeler - ICU Medical Inc. (118380146)

Revised: 10/2020

ICU Medical Inc.