LACTATED RINGERS- sodium chloride, soldium lactate, potassium chloride and calcium chloride irrigant
Baxter Healthcare Corporation

Lactated Ringer's Irrigation
in ARTHROMATIC Plastic Container

DESCRIPTION

Lactated Ringer's Irrigation is a sterile, nonpyrogenic, isotonic solution in a single dose ARTHROMATIC plastic container for use as an arthroscopic irrigating solution. Each liter contains 6.0 g Sodium Chloride, USP, (NaCl), 3.1 g Sodium Lactate ($C_3H_5NaO_3$), 300 mg Potassium Chloride, USP, (KCl), and 200 mg Calcium Chloride, USP, ($CaCl_2 \cdot 2H_2O$). pH 6.5 (6.0 to 7.5). Milliequivalents per liter: Sodium - 130, Potassium - 4, Calcium - 3, Chloride - 109, Lactate - 28. Osmolarity 273 mOsmol/L (calc.). No antimicrobial agent has been added.

The ARTHROMATIC plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexylphthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Lactated Ringer's Irrigation is useful as an irrigating fluid for body joints because it approximates the electrolyte composition of synovial fluid, and provides a transparent fluid medium with optical properties suitable for good visualization of the interior joint surface during endoscopic examination. During arthroscopic surgical procedures, the solution acts as a lavage for removing blood, tissue fragments, and bone fragments.

INDICATIONS AND USAGE

Lactated Ringer's Irrigation is indicated for use as an arthroscopic irrigating fluid with endoscopic instruments during arthroscopic procedures requiring distension and irrigation of the knee, shoulder, elbow, or other bone joints.

CONTRAINDICATIONS

Lactated Ringer's Irrigation is contraindicated in patients with a known hypersensitivity to Sodium Lactate.

WARNINGS

Absorption of large volume of irrigation fluids through a perforation or open wound may result in circulatory overload, cardiac failure, or electrolyte disturbances and acid-base imbalance.

Patients and fluid balance should be monitored accordingly. If absorption of clinically relevant amounts of fluid is suspected, the fluid administration should be interrupted, and the patient evaluated for possible adverse consequences.

Particularly close monitoring is required in patients with:

- Severely impaired renal function
- Impaired cardiac function, or
- Clinical states in which there is edema with sodium retention as a fluid overload syndrome may develop in these patients following absorption of even small quantities of irrigation fluid.

Appropriate therapy should be initiated, as indicated.

Lactated Ringer's Irrigation must not be used when types of electrocautery are used that are not safe and effective when performed in the presence of electrolyte solutions.

Excessive volume or pressure during irrigation may cause excessive fluid absorption, undue distention of cavities, and/or disruption of tissue.

PRECAUTIONS

The container must not be vented.

Vented administration sets with the vent in the open position should not be used with flexible plastic containers. Use of a vented administration set with the vent in the open position could result in air embolism.

Pressurizing solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

Drug Interactions

If clinically relevant amounts of solution have been absorbed, potential interactions with other agents must be considered, such as:

Patients treated with drugs that may increase the risk of sodium and fluid retention, such as corticosteroids and carbenoxolone, may have an increased risk of sodium and fluid retention.

Due to the alkalinizing action of lactate (formation of bicarbonate), Lactated Ringer's Irrigation may interfere with the elimination of drugs for which renal elimination is pH dependent:

- Renal clearance of acidic drugs such as salicylates, barbiturates, and lithium may be increased.
- Renal clearance of alkaline drugs, such as sympathomimetics (e.g., ephedrine,

pseudoephedrine), dextroamphetamine (dexamphetamine) sulfate, and fenfluramine (phenfluramine) hydrochloride may be decreased.

The risk of hyperkalemia is increased in patients treated with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia, such as potassium-sparing diuretics (amiloride, spironolactone, triameterene), with ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine.

Administration of potassium in patients treated with such medications can produce severe and potentially fatal hyperkalemia, particularly in patients with severe renal insufficiency.

Absorption of calcium-containing solutions may increase the effects of digitalis and lead to serious or fatal cardiac arrhythmia.

In patients treated with thiazide diuretics or vitamin D, the risk of hypercalcemia is increased.

Pregnancy

Teratogenic Effects

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

Nursing Mothers

There is no adequate data from the use of Lactated Ringer’s Irrigation in lactating women. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing Lactated Ringer’s Irrigation.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established by adequate and well-controlled trials.

Geriatric Use

When selecting the type of irrigation solution and the volume, duration of irrigation, and pressure for a geriatric patient, consider that geriatric patients are more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

ADVERSE REACTIONS

Post-Marketing Adverse Reactions

No adverse reactions were identified in Baxter’s Adverse Event Reporting System database with Lactated Ringer’s Irrigation.

Class Reactions

Adverse reactions reported with Lactated Ringer’s Irrigation (manufacturer unspecified)

are: Fluid absorption manifested by Pulmonary edema, Edema, and Electrolyte disturbances.

Though not indicated for intravenous administration, absorption of irrigation fluid into tissue or vasculature through a perforation or open wound is possible. As a result, adverse reactions reported with Lactated Ringer's solutions with and without Dextrose for intravenous administration may be applicable and include:

- Hypersensitivity reactions, including Anaphylactic/Anaphylactoid reactions, with the following manifestations: Angioedema, Chest pain, Chest discomfort, Decreased heart rate, Tachycardia, Blood pressure decreased, Respiratory distress, Bronchospasm, Dyspnea, Cough, Urticaria, Rash, Pruritus, Erythema, Flushing, Throat irritation, Paresthesias, Hypoesthesia oral, Dysgeusia, Nausea, Anxiety, Headache, Hyperkalemia
- Pyrexia

Overdose

In the event of clinically relevant absorption of irrigation fluid, the patients must be evaluated and corrective measures instituted as appropriate.

DOSAGE AND ADMINISTRATION

The volume and/or rate of solution needed will vary with the nature and duration of the arthroscopic procedure.

This solution, as it is packaged, is not intended for IV administration or injection.

The container must not be vented (See Precautions).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact. If particulate matter or discoloration is found, contact Baxter Customer Service

Aseptic technique should be used when applying this product.

The contents of an opened container should be used promptly to minimize the possibility of bacterial growth or pyrogen formation. Discard the unused portion of irrigating solution since no antimicrobial agent has been added.

When using Lactated Ringer's Irrigation for pour irrigation, prevent contact of the fluid with the external surface of the container.

Lactated Ringer's Irrigation is for single-patient use only.

Microwave heating of irrigation fluids is not recommended. If desired, Lactated Ringer's Irrigation may be warmed in a water bath or oven to not more than 45° C while maintaining sterility. Lactated Ringer's Irrigation that has been warmed must not be returned to storage.

Cetriaxone must not be mixed with calcium-containing solutions, including Lactated Ringer's Irrigation.

Additives may be incompatible with Lactated Ringer's Irrigation. Additives known or

determined to be incompatible should not be used.

As with all parenteral solutions, compatibility of the additives with the solution must be assessed before addition, by checking for, for example, a possible color change and/or the appearance of precipitates, insoluble complexes, or crystals. Before adding a substance or medication, verify that it is soluble and/or stable in water and that the pH range of Lactated Ringer's Irrigation is appropriate.

The instructions for use of the medication to be added and other relevant literature must be consulted.

When making additions to Lactated Ringer's Irrigation, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

Lactated Ringer's Irrigation in ARTHROMATIC Plastic Container is available as follows:

2B7487	3000 mL	NDC 0338-0137-27
2B7489	5000 mL	NDC 0338-0137-29

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

DIRECTIONS FOR USE

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

Use Aseptic Technique.

1. Suspend container using hanger hole.
2. Remove protector from outlet port.
3. Attach irrigation set. Refer to complete directions accompanying set.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Printed in USA

07-19-00-0210 Rev. January 2018

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL

Container Label

NOT FOR INJECTION

5000 mL

2B7489

NDC 0338-0137-29

Lactated Ringers

IRRIGATION

EACH 100 mL CONTAINS 600 mg SODIUM CHLORIDE USP 310 mg SODIUM LACTATE 30 mg POTASSIUM CHLORIDE USP 20 mg CALCIUM CHLORIDE USP NO ANTIMICROBIAL AGENT HAS BEEN ADDED pH 6.5 (6.0 to 7.5) mEq/L SODIUM 130 POTASSIUM 4 CALCIUM 3 CHLORIDE 109 LACTATE 28 OSMOLARITY 273 mOsmol/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER

DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION

CAUTIONS SQUEEZE AND INSPECT INNER BAG WHICH

MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND **RX ONLY** STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT

Lactated Ringers

IRRIGATION

ARTHROMATIC CONTAINER

PL 146 PLASTIC

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA

BAXTER ARTHROMATIC AND
PL 146 ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC

FOR PRODUCT INFORMATION
1-800-933-0303

LACTATED RINGERS

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-0137
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	6 g in 1000 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	3.1 g in 1000 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	300 mg in 1000 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	200 mg in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0137-29	5000 mL in 1 BAG; Type 0: Not a Combination Product	04/03/1984	
2	NDC:0338-0137-27	3000 mL in 1 BAG; Type 0: Not a Combination Product	04/03/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018921	04/03/1984	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	ANALYSIS(0338-0137) , MANUFACTURE(0338-0137) , LABEL(0338-0137) , PACK(0338-0137) , STERILIZE(0338-0137) , API MANUFACTURE(0338-0137)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0137)