

RINGERS IRRIGATION- sodium chloride, potassium chloride, and calcium chloride irrigant injection, solution
ICU Medical Inc.

Ringer's Irrigation, USP

FOR ALL GENERAL IRRIGATION, WASHING AND RINSING PURPOSES

Not For Injection By Usual Parenteral Routes

Semi-rigid Irrigation Container

Rx only

DESCRIPTION

These products are sterile, nonpyrogenic solutions of electrolytes in water for injection intended only for sterile irrigation, washing and rinsing purposes.

Each 100 mL of Ringer's Irrigation, USP contains: Sodium chloride 860 mg; potassium chloride 30 mg; calcium chloride dihydrate 33 mg. The pH is 5.7 (5.0 — 7.5). The solution is isotonic (309 mOsmol/liter, calc.) and has the following electrolyte content (mEq/liter): Na⁺ 147.5; K⁺ 4; Ca⁺⁺ 4.5; Cl⁻ 156.

The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as single-dose or short procedure irrigation. When smaller volumes are required the unused portion should be discarded. Ringer's Irrigation, USP 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.

Water for Injection, USP is chemically designated H₂O.

The semi-rigid container is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The container requires no vapor barrier to maintain the proper drug concentration.

Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

Ringer's Irrigation, USP 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.

Ringer's Irrigation, USP provides an isotonic irrigation with the same ionic constituents as Ringer's Injection, USP, a modification of Ringer's solution (also called Ringer's mixture) originally used only as a topical physiologic salt solution.

Ringer's Irrigation, USP 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.

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

Ringer's Irrigation, USP 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 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.

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 semi-rigid wide mouth 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.

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

Drug Interactions

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

Carcinogenesis, Mutagenesis, Impairment of Fertility:

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

Nursing Mothers:

Caution should be exercised when Ringer's Irrigation, USP is administered to a nursing woman.

Pregnancy:

Teratogenic Effects.

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

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:

Clinical studies of Ringer's Irrigation have not been performed to determine whether patients over 65 years respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

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 distention 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.

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

HOW SUPPLIED

Ringer's Irrigation, USP is supplied in a single-dose 1000 mL semi-rigid irrigation container (NDC No. 0409-6140-09; NDC No. 0990-6140-09).

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: July, 2020

EN-5962

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

PRINCIPAL DISPLAY PANEL - 1000 mL Bottle Label

1000 mL
Rx only
NDC 0990-6140-09

Ringer's
Irrigation, USP

100 mL contains sodium chloride, 860 mg; potassium chloride 30 mg; calcium chloride, dihydrate 33 mg. 309 mOsmol/liter (calc.). pH 5.7 (5.0 to 7.5). Sterile, nonpyrogenic. Not for injection. Use only if clear and seal intact. Warnings: Do not heat bottle over 66°C (150°F). Recommended storage: Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert. Single-dose container. Contains no bacteriostat. Discard unused portion. Usual dosage: See insert.

AQUALITE™ SYSTEM
Manufactured for ICU Medical, Inc.,

Lake Forest, Illinois, 60045 USA

icumedical

RL -7292

LOT

EXP

1000 mL Rx only NDC 0990-6140-09

Ringer's Irrigation, USP

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RINGERS IRRIGATION

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0990-6140
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	860 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	33 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-6140-09	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017635	09/17/2021	

Labeler - ICU Medical Inc. (118380146)

Establishment

Name	Address	ID/FEI	Business Operations
ICU MEDICAL INC.		117395980	ANALYSIS(0990-6140) , PACK(0990-6140) , LABEL(0990-6140)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Pharma Solutions, LLC		014167995	ANALYSIS(0990-6140)

