**PHYSIOSOL- sodium chloride, sodium acetate anhydrous, sodium gluconate, potassium chloride, and magnesium chloride irrigant**
**ICU Medical Inc.**

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## PHYSIOSOL™ IRRIGATION

Balanced Electrolyte Solution for Irrigation

For All General Irrigation, Washing and Rinsing Purposes

**Not for Injection By Usual Parenteral Routes**

**Semi-rigid Irrigation Container**

Rx only

## DESCRIPTION

PhysioSol™ is a sterile, nonpyrogenic solution of electrolytes in water for injection intended only for sterile irrigation, washing and rinsing purposes.

Each 100 mL of PhysioSol™ Irrigation contains sodium chloride 526 mg, sodium acetate 222 mg, sodium gluconate 502 mg, potassium chloride 37 mg, magnesium chloride hexahydrate 30 mg. The pH is 6.0 (5.0 to 6.5) adjusted with hydrochloric acid. The solution is isotonic (294 mOsmol/liter, calc.) and has the following electrolyte content (mEq/liter): $Na^+$ 140, $K^+$ 5, $Mg^{++}$ 3, $Cl^-$ 98, $HCO_3^-$ 50 alternates (27 as acetate and 23 as gluconate).

It contains no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and is intended only for use as single-dose or short procedure irrigation. When smaller volumes are required the unused portion should be discarded.

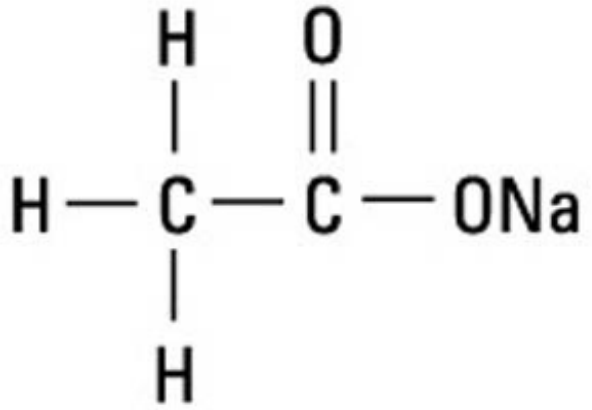
PhysioSol™ may be classified as a sterile irrigant, wash, rinse and pharmaceutical vehicle.

Magnesium Chloride, USP is chemically designated magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$), colorless, odorless flakes or crystals very soluble in water.

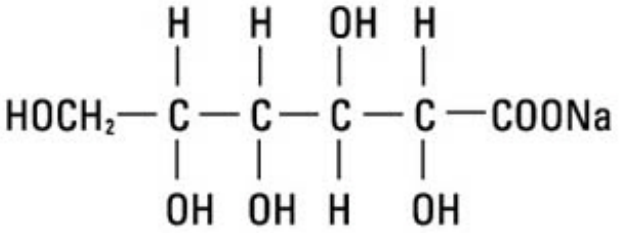
Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

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

Sodium Acetate, USP is chemically designated sodium acetate ($C_2H_3O_2Na$), colorless crystals or white crystalline powder or flakes very soluble in water. It has the following structural formula:



Sodium gluconate is chemically designated $C_6H_{11}NaO_7$, the normal sodium salt of gluconic acid soluble in water. It has the following structural formula:



Water for Injection, USP is chemically designated $H_2O$.

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 concentrations.

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

PhysioSol™ 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.

PhysioSol™ provides an isotonic calcium-free balanced electrolyte irrigation with the same ionic composition as Normosol™-R, a multiple electrolyte solution for I.V.

replacement of acute extracellular fluid losses.

PhysioSol™ Irrigation is considered generally compatible with living tissues and organs.

Magnesium chloride in water dissociates to provide magnesium ($Mg^{++}$) and chloride ($Cl^{-}$) ions. Magnesium is the second most plentiful cation of the intracellular fluids. It is an important cofactor for enzymatic reactions and plays an important role in neurochemical transmission and muscular excitability. Normal plasma concentration ranges from 1.5 to 2.5 or 3.0 mEq/liter. Magnesium is excreted solely by the kidney at a rate proportional to the plasma concentration and glomerular filtration.

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 acetate provides sodium ($Na^{+}$) and acetate ($CH_3COO^{-}$) ions, the latter anion (a source of hydrogen ion acceptors) serving as an alternate source of bicarbonate ($HCO_3^{-}$) by metabolic conversion in the liver. This has been shown to proceed readily even in the presence of severe liver disease. Thus, acetate anion exerts a mild systemic antiacidotic action that may be advantageous during fluid and electrolyte replacement therapy.

Sodium gluconate provides sodium ($Na^{+}$) and gluconate ($C_6H_{11}O_7^{-}$) ions. Although gluconate is a theoretical alternate metabolic source of bicarbonate ($HCO_3^{-}$) anion, a significant antiacidotic (alkalizing) action has not been established. Thus, the gluconate anion serves primarily to complete the cation-anion balance of the solutions.

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

PhysioSol™ 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, those irrigations 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

Caution should be observed when a 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 PhysioSol™ Irrigation have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

**Nursing Mothers:**

Caution should be exercised when PhysioSol™ Irrigation is administered to a nursing woman.

**Pregnancy:**

*Teratogenic Effects: Pregnancy Category C:* Animal reproduction studies have not been conducted with PhysioSol™ Irrigation. It is also not known whether PhysioSol™ Irrigation can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PhysioSol™ Irrigation should be given to a pregnant woman only if clearly needed.

**Pediatric Use:**

The safety and effectiveness of PhysioSol™ Irrigation pH 7.4 have not been established. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

**Geriatric Use:**

Clinical studies of PhysioSol™ 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 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.

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

## HOW SUPPLIED

PhysioSol™ Irrigation is supplied in a 1000 mL single-dose semi-rigid irrigation container. (NDC No. 0409-6141-09)

(NDC No. 0990-6141-09)

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: April, 2018

EN-5714

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

## PRINCIPAL DISPLAY PANEL - 1000 mL Bottle Label

1000 mL
NDC 0990-6141-09

**PhysioSol™**
**Irrigation**

Each **100 mL** contains sodium chloride, 526 mg; sodium acetate, anhydrous 222 mg; sodium gluconate, 502 mg; potassium chloride, 37 mg; magnesium chloride, hexahydrate 30 mg. pH adjusted with HCl. pH 6.0 (5.0 to 6.5). 294 mOsmol/liter (calc.). Sterile, nonpyrogenic. Isotonic solution for irrigation. **Contraindication:** Not for injection. Use only if clear and seal intact. **Warning:** Do not heat bottle over 66°C (150°F). Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing. See insert.

Single-dose container. **Usual dosage:** See insert.

Rx only

***AQUALITE™ SYSTEM***

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

**icu**medical

RL–7138

LOT

EXP

1000 mL

NDC 0990-6141-09

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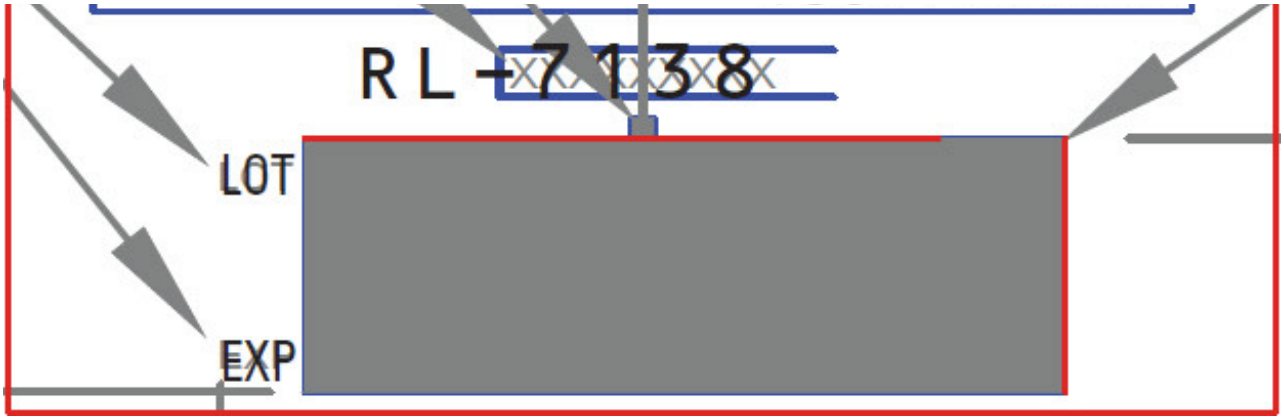
Rx only

***AQUALITE™ SYSTEM***

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

icumedical




# PHYSIOSOL

sodium chloride, sodium acetate anhydrous, sodium gluconate, potassium chloride, and magnesium chloride irrigant

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0990-6141 |
| **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 | 526 mg in 100 mL |
| **SODIUM ACETATE ANHYDROUS** (UNII: NVG71ZZ7P0) (SODIUM CATION - UNII:LYR4M0NH37) | SODIUM ACETATE ANHYDROUS | 222 mg in 100 mL |
| **SODIUM GLUCONATE** (UNII: R6Q3791S76) (SODIUM CATION - UNII:LYR4M0NH37) | SODIUM GLUCONATE | 502 mg in 100 mL |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698) | POTASSIUM CHLORIDE | 37 mg in 100 mL |
| **MAGNESIUM CHLORIDE** (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698) | MAGNESIUM CHLORIDE | 30 mg in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0990-6141-09 | 12 in 1 CASE | 07/01/2018 | |
| **1** | | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA | NDA017637 | 07/01/2018 | |

## Labeler - ICU Medical Inc. (118380146)

Revised: 1/2022 ICU Medical Inc.