SODIUM CHLORIDE- sodium chloride irrigant
ICU Medical Inc.

0.9% SODIUM CHLORIDE IRRIGATION, USP

For All General Irrigation, Washing, Rinsing and Dilution Purposes

Not For Injection By Usual Parenteral Routes

Flexible Irrigation Container

Semi-rigid Irrigation Container

R_x only

DESCRIPTION

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

Each 100 mL of 0.9% Sodium Chloride Irrigation, USP contains: Sodium chloride 900 mg; pH 5.6 (4.5 to 7.0). May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. The solution is isotonic (308 mOsmol/liter, CALC.) and has the following electrolyte content (mEq/liter): Na^+ 154; Cl^- 154.

These irrigations contain no bacteriostat, antimicrobial agent or added buffer and are intended only for use as single-dose or short procedure irrigation. When smaller volumes are required the unused portion should be discarded.

Each of these irrigations may be classified as a sterile irrigant, wash, rinse, diluent and pharmaceutical vehicle.

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

Water for Injection, USP is chemically designated H_2O.

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.

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

Each of these irrigation solutions exert 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. Each also serves as a diluent or vehicle for drugs used for irrigation or other pharmaceutical preparations.

0.9% Sodium Chloride Irrigation, USP provides an isotonic saline irrigation identical in composition with 0.9% Sodium Chloride Injection, USP (normal saline).

0.9% Sodium Chloride Irrigation, USP is considered generally compatible with living tissues and organs.

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

Each of these solutions is indicated for all general irrigation, washing, rinsing and dilution 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.

Entry of a hypotonic solution into the circulation may cause hemolysis.

Irrigating fluids have been demonstrated to enter the systemic circulation in relatively large volumes; thus each of these 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 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 a hypotonic 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 intravascular hemolysis and 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. 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, seal is intact and container is undamaged.

Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Studies with Sodium Chloride Irrigation, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers:

Caution should be exercised when Sodium Chloride Irrigation, USP is administered to a nursing woman.

Pregnancy:

Teratogenic Effects.

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

Pediatric Use:

Safety and effectiveness of Sodium Chloride irrigation solution in pediatric patients have not been established by adequate and well-controlled trials. However, the use of Sodium

Chloride irrigation solution in the pediatric population is referenced in the medical literature. The Warnings, Precautions, and Adverse Reactions identified in the label should be observed in the pediatric population.

Geriatric Use:

An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients.

This drug is known to be substantially secreted 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 diluent or 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

0.9% Sodium Chloride Irrigation, USP:

Container Size	NDC
Single-dose 500 mL semi-rigid irrigation container	0409-6138-03*
Single-dose 500 mL semi-rigid irrigation container	0990-6138-03*
Single-dose 250 mL semi-rigid irrigation container	0409-6138-22*
Single-dose 250 mL semi-rigid irrigation container	0990-6138-22*
Single-dose 1000 mL semi-rigid irrigation container	0409-7138-09*
Single-dose 1000 mL semi-rigid irrigation container	0990-7138-09*
Single-dose 1500 mL semi-rigid irrigation container	0409-7138-36*
Single-dose 1500 mL semi-rigid irrigation container	0990-7138-36*
Single-dose 1000 mL flexible irrigation container	0409-7972-05†
Single-dose 1000 mL flexible irrigation container	0990-7972-05†
Single-dose 2000 mL flexible irrigation container	0409-7972-07†
Single-dose 2000 mL flexible irrigation container	0990-7972-07†

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

ICU Medical is transitioning NDC codes from "0409" to "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, 2018

EN-4660

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

PRINCIPAL DISPLAY PANEL - 1000 mL Bottle Label

1000 mL
NDC 0990-7138-09

0.9% SODIUM
CHLORIDE
Irrigation, USP

Each 100 mL contains sodium

chloride, 900 mg. 308 mOsmol/liter (calc.). May contain NaOH and/or HCl for pH adjustment. pH 5.6 (4.5 – 7.0). Sterile, nonpyrogenic. Indications: Isotonic solution for irrigation. Contraindications: 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. Contains no bacteriostat. Discard unused portion. Usual dosage: See insert.

Rx only

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AQUALITE™ SYSTEM

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

RL-7284

LOT

EXP

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

500 mL
NDC 0990-6138-03

0.9%
SODIUM CHLORIDE
Irrigation, USP

Each 100 mL contains sodium chloride, 900 mg. 308 mOsmol/liter (calc.). May contain NaOH and/or HCl for pH adjustment. pH 5.6 (4.5–7.0). Sterile, nonpyrogenic. Isotonic solution for irrigation. Contraindications: 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. Contains no bacteriostat. Discard unused portion. Usual dosage: See insert.

Rx only

AQUALITE™ SYSTEM

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

RL-7282

LOT

EXP

PRINCIPAL DISPLAY PANEL - 2000 mL Bag Label

2000 mL
NDC 0990-7972-07

0.9% SODIUM
CHLORIDE
Irrigation , USP

EACH 100 mL CONTAINS SODIUM CHLORIDE, 900 mg.
pH 5.6 (4.5 to 7.0)
308 mOsmol/LITER (CALC.)
STERILE, NONPYROGENIC.
INDICATIONS: ISOTONIC SOLUTION FOR IRRIGATION.
CONTRAINDICATIONS: NOT FOR

INJECTION. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED.
WARNINGS:
DO NOT HEAT OVER 66°C (150°F).
STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.]
PROTECT FROM FREEZING.
SINGLE-DOSE CONTAINER.
CONTAINS NO BACTERIOSTAT.
DISCARD UNUSED PORTION. USE ASEPTIC TECHNIQUE.
DOSAGE AND ADMINISTRATION:
AS DIRECTED BY PHYSICIAN.

RX ONLY

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CONTAINS DEHP

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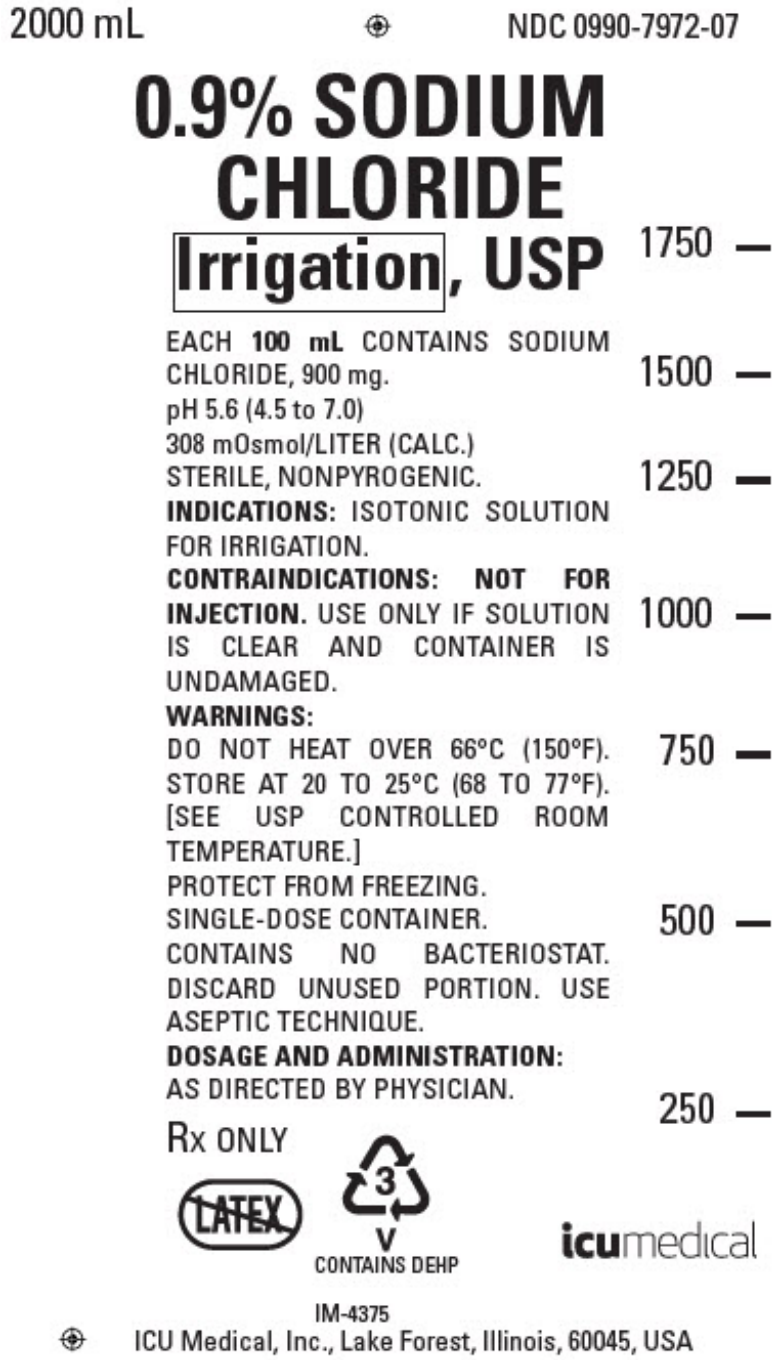
IM-4375

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



PRINCIPAL DISPLAY PANEL - 2000 mL Bag Overwrap

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

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

SODIUM CHLORIDE

sodium chloride irrigant

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7138
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	900 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:0990-7138-09	12 in 1 CASE	09/01/2019	
1		1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0990-7138-36	9 in 1 CASE	01/01/2020	
2		1500 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	NDA017514	08/01/2019	

SODIUM CHLORIDE

sodium chloride irrigant

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-6138
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	900 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:0990-6138-22	24 in 1 CASE	10/01/2019	
1		250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0990-6138-03	24 in 1 CASE	10/01/2019	
2		500 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	NDA017514	08/01/2019	

SODIUM CHLORIDE

sodium chloride irrigant

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-7972
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	900 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:0990-7972-05	12 in 1 CASE	01/01/2020	
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:0990-7972-07	6 in 1 CASE	08/01/2019	
2		2000 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	NDA018314	08/01/2019	

Labeler - ICU Medical Inc. (118380146)

Revised: 10/2020 ICU Medical Inc.