0.9% Sodium Chloride Irrigation, USP

FOR ALL GENERAL IRRIGATION, RINSING, DILUTION AND CELL WASHING PURPOSES

Not For Injection By Usual Parenteral Routes

Flexible Irrigation Container

Rx only

DESCRIPTION

This product is a sterile, nonpyrogenic solution of electrolytes in water for injection intended only for sterile irrigation, rinsing, dilution and cell washing purposes.

Each 100 mL of 0.9% Sodium Chloride Irrigation, USP contains: Sodium chloride 900 mg. pH 5.6 (4.5 — 7.0). The solution is isotonic (308 mOsmol/liter, calc.) and has the following electrolyte content (mEq/liter): Na^+ 154; Cl^- 154.

This irrigation solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose, short procedure irrigation, or cell washing fluid. When smaller volumes are required the unused portion should be discarded.

It may be classified as a sterile irrigant, rinse, diluent, cell wash 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. 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

This irrigation solution 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 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 requirements 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

This sterile, nonpyrogenic electrolyte solution is indicated for all general irrigation, washing, rinsing and dilution purposes including blood cell washing (when used in conjunction with automated intraoperative blood salvaging equipment).

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 over 66° C (150° F).

PRECAUTIONS

Do not use for irrigation that may result in absorption into the blood.

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 or for cell washing techniques.

The flexible container is designed for use with nonvented irrigation sets or nonvented sets for cell washing harvesting systems. When used for irrigation via irrigation equipment, the administration set should be attached promptly. Unused portions should be discarded and a fresh container 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. When used for cell washing, the nonvented set should be attached promptly. The three liter container may be used to dispense new aliquots of washing solution for each wash cycle for the same patient. However, unused portions should be discarded and a separate container should be used for each patient and each start-up procedure.

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. This solution 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, cells 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. For use in cell washing, the manufacturer's recommendations for blood salvaging and red cell processing 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 is supplied in a single-dose 3000 mL flexible irrigation container (NDC No. 0409-7972-08).

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

Revised: January, 2010

Printed in USA EN-2369

Hospira, Inc., Lake Forest, IL 60045 USA

IM-1154

3000 mL

NDC 0409-7972-08

0.9% SODIUM CHLORIDE

Irrigation, USP

2750

2500

2250

2000

1750

1500

1250

1000

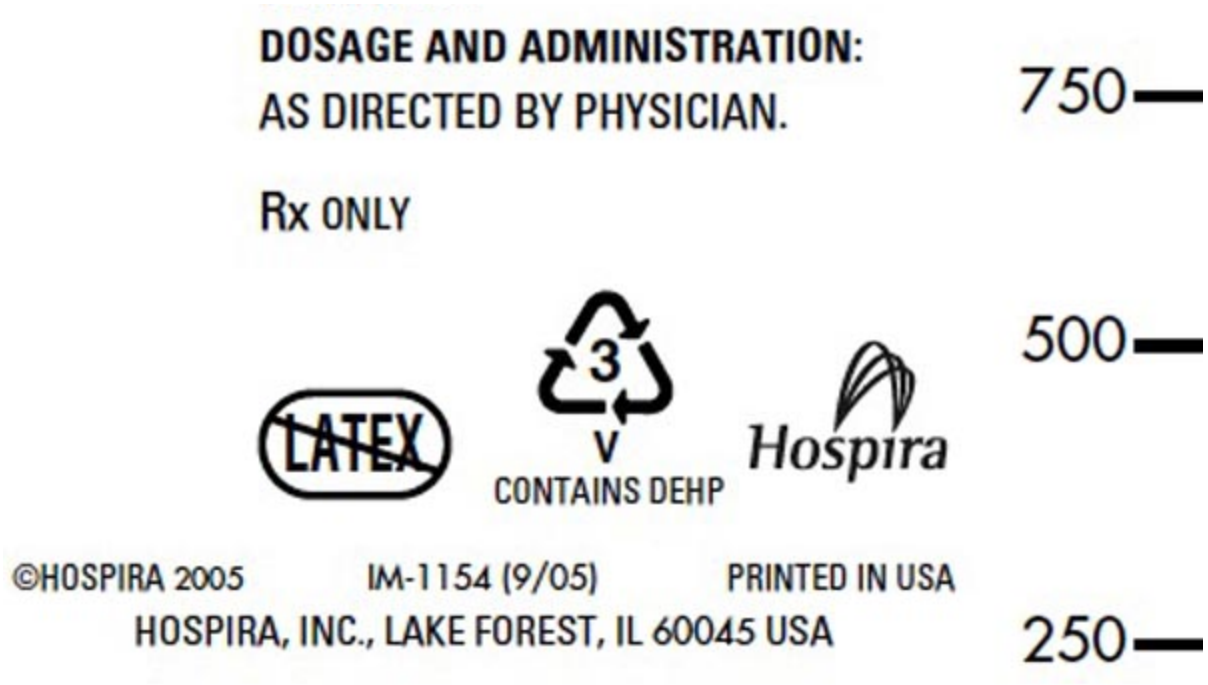
EACH **100 mL** CONTAINS SODIUM CHLORIDE, 900 mg.
pH 5.6 (4.5 to 7.0)
308 mOsmol/LITER (CALC.)
STERILE, NONPYROGENIC.

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.

(01) 0 30409 797208 1



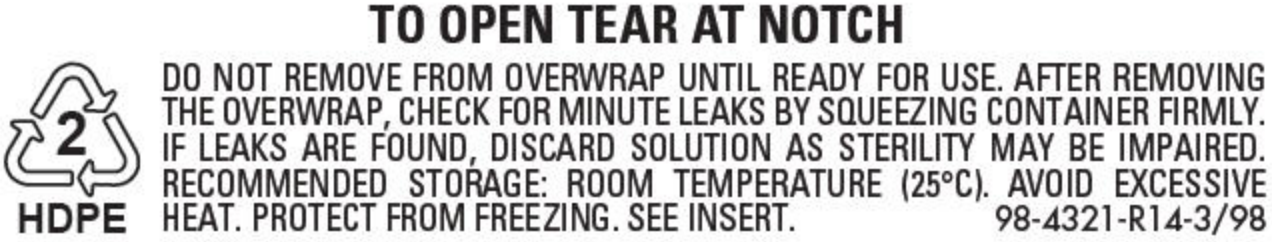
PRINCIPAL DISPLAY PANEL - 3000 mL Bag Overwrap

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



SODIUM CHLORIDE sodium chloride irrigant	
Product Information	

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-7972
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:0409-7972-08	4 in 1 CASE	05/10/2005	
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	NDA018314	05/10/2005	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-7972)

Revised: 3/2017 Hospira, Inc.