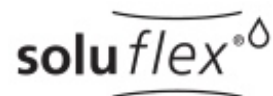


SODIUM CHLORIDE- sodium chloride injection, solution
Fresenius Kabi USA, LLC



0.9% Sodium Chloride Irrigation, USP

Isotonic Solution for Irrigation.

For Irrigation Only.

Not for Injection.

Rx only

DESCRIPTION

Each 100 mL contains:

Sodium Chloride, USP 0.9 g; Water for Injection, USP qs pH adjusted with Hydrochloric Acid, NF

pH: 5.75 (4.50-7.00)

Calculated Osmolarity: 308 mOsmol/liter

Concentration of Electrolytes (mEq/liter): Sodium 154; Chloride 154

0.9% Sodium Chloride Irrigation, USP is sterile, nonpyrogenic, isotonic and contains no bacteriostatic or antimicrobial agents.

The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Sodium Chloride, USP	NaCl	58.44

The flexible plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers. The solution contact layer is a copolymer of ethylene and propylene. The container is nontoxic and biologically inert.

The container-solution unit is a closed system and is not dependent upon entry of external air during administration.

Not made with natural rubber latex, PVC or DEHP.

CLINICAL PHARMACOLOGY

0.9% Sodium Chloride Irrigation is utilized for a variety of clinical indications such as

sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters, 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 provides an isotonic saline irrigation identical in composition with 0.9% Sodium Chloride Injection (normal saline).

Physiological irrigation solutions are considered generally compatible with living tissues and organs.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

INDICATIONS AND USAGE

0.9% Sodium Chloride Irrigation is indicated for all general irrigation, washing, rinsing and dilution purposes which permit use of a sterile, nonpyrogenic electrolyte solution.

CONTRAINDICATIONS

0.9% Sodium Chloride Irrigation is 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, irrigation solutions must be regarded as systemic drugs.

Absorption of large amounts can cause fluid and/or solute overload 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 the administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

Do not warm container above 140°F (60°C).

After opening container, its contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation.

Discard unused portion of irrigating solution since it contains no preservatives.

PRECAUTIONS

General

Use aseptic technique when preparing and administering sterile irrigation solutions. Use only if solution is clear and container and seal are intact.

Do not use for irrigation that may result in absorption of large amounts of fluid 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.

When used for irrigation via appropriate 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.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance after prolonged irrigation, when fluid absorption is suspected, or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique. Mix thoroughly. Do not store.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with 0.9% Sodium Chloride Irrigation have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Irrigation. It is also not known whether 0.9% Sodium Chloride Irrigation can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 0.9% Sodium Chloride Irrigation should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Safety and effectiveness of 0.9% Sodium Chloride Irrigation during labor and delivery have not been established. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 0.9% Sodium Chloride Irrigation is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of 0.9% Sodium Chloride Irrigation in pediatric patients 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 0.9% Sodium Chloride Irrigation did not include a sufficient number of patients age 65 years and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, 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. Frequent laboratory determinations and clinical evaluations are recommended to monitor changes in blood glucose, electrolyte concentrations, and renal function.

ADVERSE REACTIONS

Possible adverse effects arising from the irrigation of body cavities, tissues, or indwelling catheters and tubes can be minimized 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.

If an adverse reaction does occur, discontinue administration of the irrigant, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

In the event of overhydration or solute overload, reevaluate the patient's condition, and institute appropriate corrective treatment. Intravascular volume overload may respond to hemodialysis. See **WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.**

DOSAGE AND ADMINISTRATION

As required for irrigation.

When used as a diluent, or vehicle for other drugs, the drug manufacturer's recommendations should be followed.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Solutions should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permits.

HOW SUPPLIED

0.9% Sodium Chloride Irrigation, USP is supplied sterile and nonpyrogenic in single-dose flexible plastic containers.

Product Code	Unit of Sale	Each
502010	NDC 65219-502-10 Package of 6 bags	NDC 65219-502-01 1000 mL fill in a 1500 mL bag
504020	NDC 65219-504-20 Package of 5 bags	NDC 65219-504-02 2000 mL fill in a 2000 mL bag
506030	NDC 65219-506-30 Package of 4 bags	NDC 65219-506-03 3000 mL fill in a 3000 mL bag

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20 to 25°C (68 to 77°F) [see USP Controlled Room Temperature]; however, brief exposure up to 40°C (104°F) does not adversely affect the product.

Do not warm container above 140°F (60°C).

INSTRUCTIONS FOR USE:

Not for Injection. Not for use with pressurized irrigation systems.

Check solution container composition, lot number, and expiry date.

Irrigation solutions should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Do not use if the solution is cloudy or precipitate is present.

Check the solution container for leaks by squeezing firmly. If leaks are found, discard.

The intact port cap provides visual tamper evidence. Do not use if port cap is prematurely removed. Maintain strict aseptic technique during handling.

To Add Medication:

1. Identify WHITE Additive Port with arrow pointing toward solution container.
2. Immediately before injecting additives, break off WHITE Additive Port Cap with the

- arrow pointing toward solution container.
3. Hold base of WHITE Additive Port.
 4. Insert needle (18 - 23 gauge) through the center of the WHITE Additive Port's resealable septum and inject additives.
 5. Mix solution container contents thoroughly.
 6. WHITE additive port must be swabbed with disinfection agent before repuncturing.
 7. Check admixture visually for particulate matter.

Preparation for Administration

1. Immediately before inserting the irrigation set, break of BLUE Administration Port Cap with the arrow pointing away from the solution container.
2. Use non-vented irrigation set or close the air-inlet on a vented set. Refer to directions for use accompanying the irrigation set.
3. Hold the base of the BLUE Administration Port, twist and push spike until fully inserted.
4. The BLUE Administration Port contains a self-sealing septum that helps prevent leakage after removing the spike. The Administration Port is not intended to be spiked more than once.
5. Suspend solution container from hanger hole.
6. For Single Use Only. Discard unused portion.

Manufactured for:



Lake Zurich, IL 60047

Made in Germany

www.fresenius-kabi.com/us

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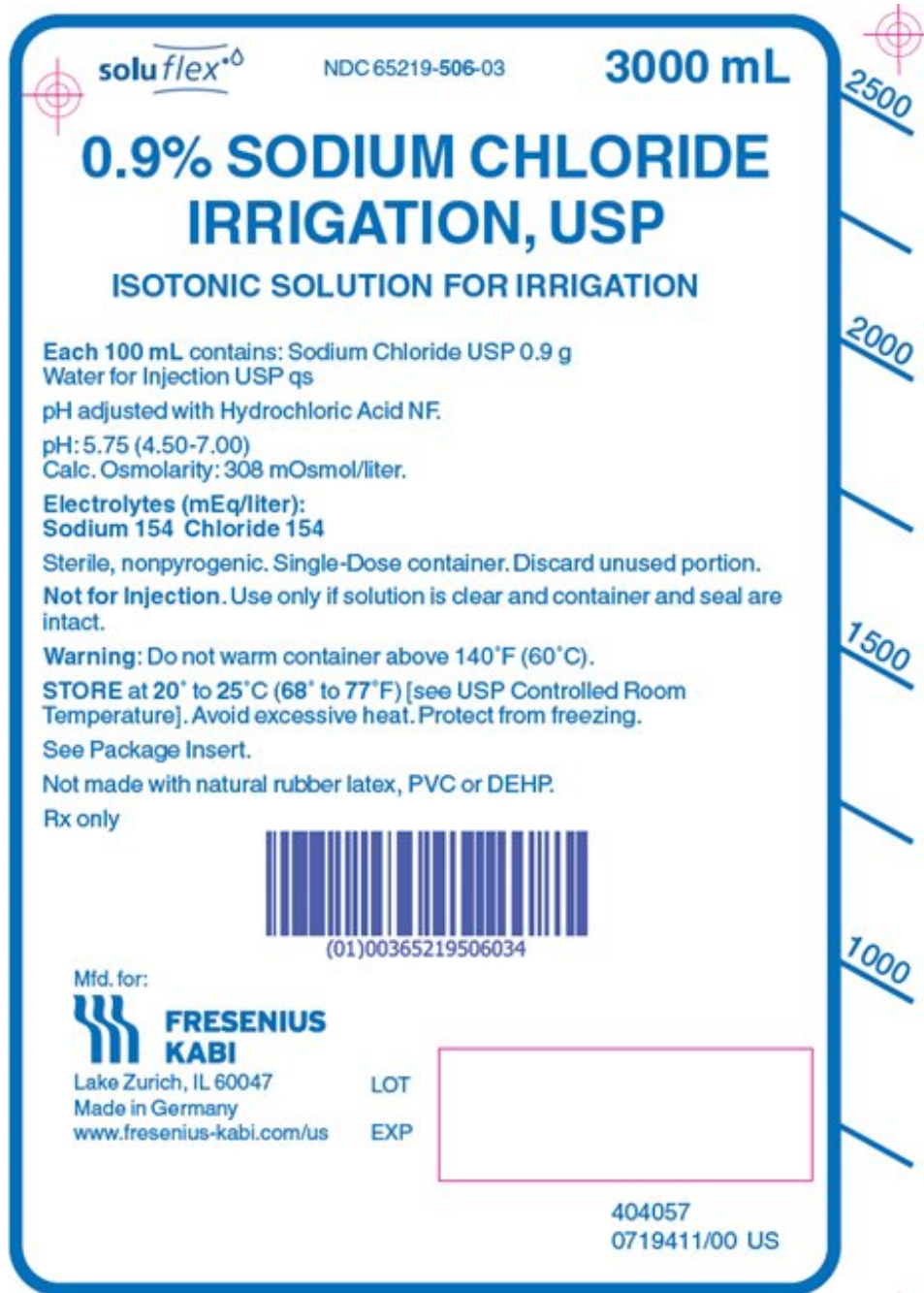
Issued: August 2024

**PACKAGE LABEL - PRINCIPAL DISPLAY - 0.9% Sodium Chloride Irrigation, USP
3000 mL Bag Label**

soluflex[®] NDC 65219-506-03 3000 mL

0.9% SODIUM CHLORIDE IRRIGATION, USP

ISOTONIC SOLUTION FOR IRRIGATION



**PACKAGE LABEL - PRINCIPAL DISPLAY - 0.9% Sodium Chloride Irrigation, USP
3000 mL Case Label**

NDC 65219-506-30 506030

0.9% Sodium Chloride Irrigation, USP

3,000 mL x 4

STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]

Avoid excessive heat. Protect from freezing.

NDC 65219-506-30

506030

0.9% Sodium Chloride Irrigation, USP

3,000 mL x 4

QTY 4

STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]
Avoid excessive heat. Protect from freezing.

Manufactured for:


**FRESENIUS
KABI**

Fresenius Kabi USA, LLC
Lake Zurich, IL 60047
www.fresenius-kabi.com/us
Made in Germany



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LOT
EXP

2nd. Barcode (GS1 128)
will be printed during production.

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65219-506
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	0.9 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:65219			

1	NDC:65219-506-30	4 in 1 CASE	06/24/2024	
1	NDC:65219-506-03	3000 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA213688		06/24/2024	

Labeler - Fresenius Kabi USA, LLC (013547657)

Establishment			
Name	Address	ID/FEI	Business Operations
Fresenius Kabi Deutschland GmbH		506719546	ANALYSIS(65219-506) , MANUFACTURE(65219-506) , API MANUFACTURE(65219-506)

Revised: 11/2024

Fresenius Kabi USA, LLC