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

0.9% Sodium Chloride Injection, USP

Rx only

DESCRIPTION:

0.9% Sodium chloride injection, USP solutions are sterile and nonpyrogenic. They are parenteral solutions containing various concentrations of sodium chloride in water for injection intended for intravenous administration.

For 0.9% Sodium chloride injection, USP, each 100 mL contains 900 mg sodium chloride in water for injection. Electrolytes per 1,000 mL: sodium 154 mEq; chloride 154 mEq. The osmolarity is 308 mOsmol/L (calc.).

The pH range is 4.5 to 7.0 for all containers.

The solutions contain no bacteriostat, antimicrobial agent or added buffer and each is intended only as a single-dose injection. When smaller doses are required the unused portion should be discarded.

The solutions are parenteral fluid and electrolyte replenishers.

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 container is fabricated from a specially formulated non-plasticized, film containing polypropylene and thermoplastic elastomers (***free****flex*® bag). The amount of water that can permeate from the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the flexible container can leach out certain of the container's chemical components in very small amounts within the expiration period. The suitability of the container material has been confirmed by tests in animals according to USP biological tests for plastic containers.

CLINICAL PHARMACOLOGY:

When administered intravenously, these solutions provide a source of water and electrolytes.

Solutions which provide combinations of hypotonic or isotonic concentrations of sodium chloride are suitable for parenteral maintenance or replacement of water and electrolyte requirements.

Isotonic concentrations of sodium chloride are suitable for parenteral replacement of chloride losses that exceed or equal the sodium loss. Hypotonic concentrations of sodium chloride are suited for parenteral maintenance of water requirements when only small quantities of salt are desired. A hypertonic concentration of sodium chloride may be used to repair severe salt depletion syndrome.

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 range from two to three liters (1 to 1.5 liters each for insensible water loss by perspiration and urine production).

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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:

Intravenous solutions containing sodium chloride are indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient.

CONTRAINDICATIONS:

None known.

WARNINGS:

Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

Excessive administration of potassium-free solutions may result in significant hypokalemia.

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

The intravenous administration of these solutions 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.

PRECAUTIONS:

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions to patients receiving corticosteroids or corticotropin.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with sodium chloride to evaluate the potential for carcinogenesis, mutagenesis or impairment of fertility.

Pregnancy

Teratogenic Effects

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

Nursing Mothers

Caution should be exercised when sodium chloride is administered to a nursing woman.

Pediatric Use

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

ADVERSE REACTIONS:

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, 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 age, weight and clinical condition of the patient.

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 and container permit (see **PRECAUTIONS**).

INSTRUCTIONS FOR USE:

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

Do not remove solution container from its overwrap until immediately before use.

Use sterile equipment and aseptic technique.

To Open

1. Turn solution container over so that the text is face down. Using the pre-cut corner tabs, peel open the overwrap and remove solution container.
2. Check the solution container for leaks by squeezing firmly. If leaks are found, or if the seal is not intact, discard the solution.
3. Do not use if the solution is cloudy or a precipitate is present.

To Add Medication

1. Identify WHITE Additive Port with arrow pointing toward container.
2. Immediately before injecting additives, break off WHITE Additive Port Cap with the arrow pointing toward container.
3. Hold base of WHITE Additive Port horizontally.
4. Insert needle horizontally through the center of WHITE Additive Port's septum and inject additives.
5. Mix container contents thoroughly.

Preparation for Administration

1. Immediately before inserting the infusion set, break off BLUE Infusion Port Cap with the arrow

pointing away from container.
2. Use a non-vented infusion set or close the air-inlet on a vented set.
3. Close the roller clamp of the infusion set.
4. Hold the base of BLUE Infusion Port.
5. Insert spike through BLUE Infusion Port by rotating wrist slightly until the spike is inserted.
NOTE: See full directions accompanying administration set.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED:

0.9% Sodium chloride injection, USP is supplied in single-dose flexible plastic containers as follows:

Product No.	NDC No.	Strength	Fill Sizes	Bag Size
623153	63323-623-53	0.9% (9 mg/mL)	50 mL	100 mL
623161	63323-623-61	0.9% (9 mg/mL)	100 mL	100 mL
623174	63323-623-74	0.9% (9 mg/mL)	250 mL	250 mL
623175	63323-623-75	0.9% (9 mg/mL)	500 mL	500 mL
623176	63323-623-76	0.9% (9 mg/mL)	1,000 mL	1,000 mL

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

This container is not made with natural rubber latex or polyvinyl chloride (PVC), Non-DEHP.

Manufactured for:

FRESENIUS KABI

Lake Zurich, IL 60047

www.fresenius-kabi.us

August 2016

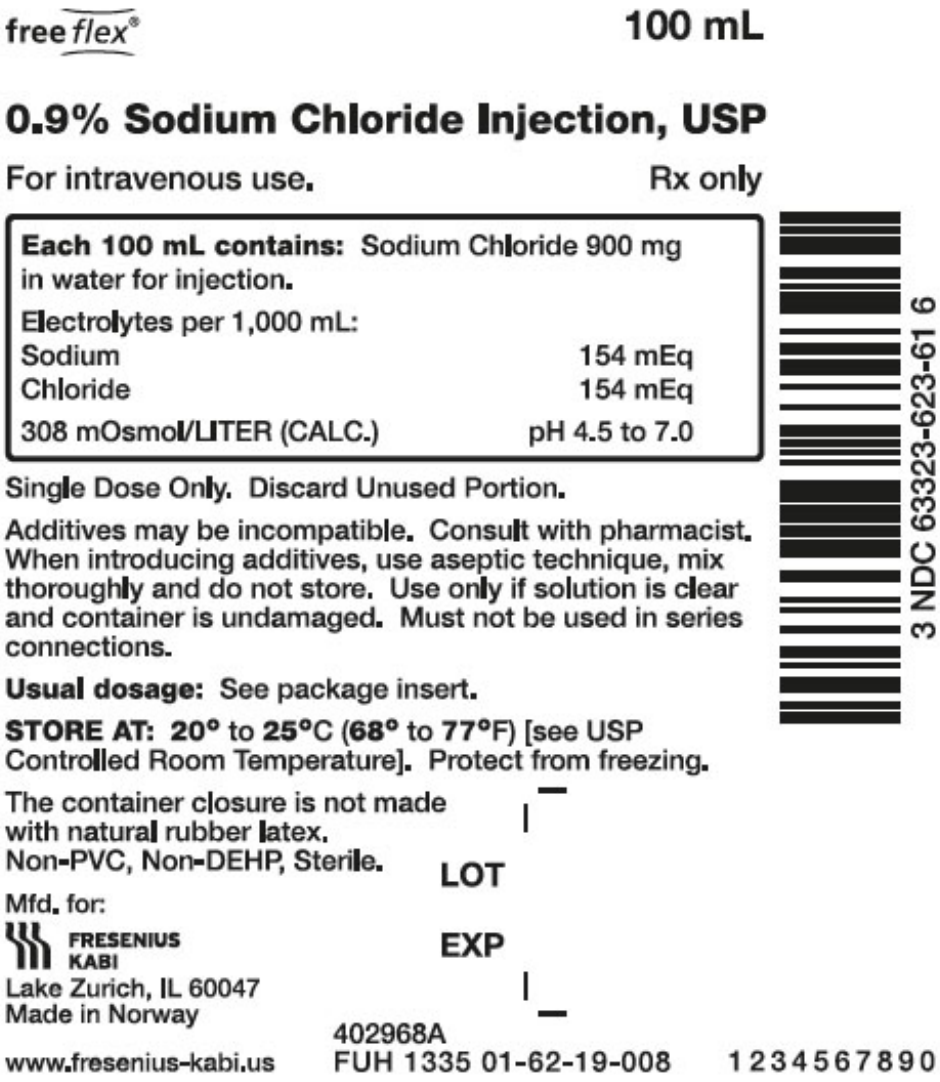
PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Sodium Chloride 100 mL Bag Label

free flex®

100 mL

0.9% Sodium Chloride Injection, USP

For intravenous use.
Rx only



SODIUM CHLORIDE

sodium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-623
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63323-623-53	50 mL in 1 BAG; Type 0: Not a Combination Product	09/19/2017	

2	NDC:63323-623-61	100 mL in 1 BAG; Type 0: Not a Combination Product	09/19/2017	
3	NDC:63323-623-74	250 mL in 1 BAG; Type 0: Not a Combination Product	09/19/2017	
4	NDC:63323-623-75	500 mL in 1 BAG; Type 0: Not a Combination Product	09/19/2017	
5	NDC:63323-623-76	1000 mL in 1 BAG; Type 0: Not a Combination Product	09/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207310	09/19/2017	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Norge AS		731170932	ANALYSIS(63323-623) , MANUFACTURE(63323-623)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Deutschland GmbH		506719546	ANALYSIS(63323-623) , MANUFACTURE(63323-623)

Revised: 1/2020 Fresenius Kabi USA, LLC