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

Bacteriostatic Sodium Chloride Injection, USP

0.9%

NOT FOR USE IN NEWBORNS

DESCRIPTION

Bacteriostatic Sodium Chloride Injection, USP, 0.9% is a sterile, nonpyrogenic, isotonic solution.

Each mL contains: Sodium chloride 9 mg; benzyl alcohol 0.9%; Water for Injection q.s. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment (pH 4.5-7.0).

Sodium chloride occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium chloride is freely soluble in water. It is soluble in glycerin and slightly soluble in alcohol.

The empirical formula for sodium chloride is NaCl and the molecular weight is 58.44.

CLINICAL PHARMACOLOGY

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

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.

The small volume of fluid and amount of sodium chloride provided by Bacteriostatic Sodium Chloride Injection, USP, 0.9%, when used only as a vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in very small infants.

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 to 1.5 liters each of 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

These parenteral preparations are indicated only for diluting or dissolving drugs for

intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered. *NOT FOR INHALATION*.

CONTRAINDICATIONS

Due to potential toxicity of benzyl alcohol in newborns, Bacteriostatic Sodium Chloride Injection, USP, 0.9% containing benzyl alcohol must not be used in this patient population.

Bacteriostatic Sodium Chloride Injection, USP, 0.9% should not be used for fluid or sodium chloride replacement.

WARNINGS

Benzyl alcohol as a preservative in Bacteriostatic Sodium Chloride Injection, USP, 0.9% has been associated with toxicity in newborns. Data is unavailable on the toxicity of other preservatives in this age group. Preservative-free Sodium Chloride Injection, USP, 0.9% should be used for flushing intravascular catheters. Where a sodium chloride solution is required for preparing or diluting medications for use in newborns, only preservative-free Sodium Chloride Injection, USP, 0.9% should be used.

PRECAUTIONS

General

Bacteriostatic Sodium Chloride Injection, USP, 0.9% should not be used for those medicinals that specify the use of only Sodium Chloride Injection, USP, 0.9% as a sterile solvent.

Sodium chloride must be used with caution in the presence of congestive heart failure, circulatory insufficiency, kidney dysfunction or hypoproteinemia.

Excessive amounts of sodium chloride by any route may cause hypopotassemia and acidosis. Excessive amounts by the parenteral route may precipitate congestive heart failure and acute pulmonary edema, especially in patients with cardiovascular disease and in patients receiving corticosteroids or corticotropin or drugs that may give rise to sodium retention.

Pregnancy

Pregnancy Category C—

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

ADVERSE REACTIONS

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.

Reactions which may occur because of Bacteriostatic Sodium Chloride Injection, USP, 0.9%, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures and if possible, retrieve and save the remainder of the unused vehicle for examination.

Although adverse reactions to intravenous, intramuscular or subcutaneous injection of 0.9% benzyl alcohol are not known to occur in man, experimental studies of small volume parenteral preparations containing 0.9% benzyl alcohol in several species of animals have indicated that an estimated intravenous dose up to 30 mL may be safely given to an adult without toxic effects. Administration of an estimated 9 mL to a 6 kg infant is potentially capable of producing blood pressure changes.

OVERDOSAGE

Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of sodium chloride or fluid overload except possibly in very small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures. See **PRECAUTIONS** and **ADVERSE REACTIONS**.

DOSAGE AND ADMINISTRATION

NOT FOR INHALATION. Before Bacteriostatic Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, specific references should be checked for any possible incompatibility with sodium chloride or benzyl alcohol.

The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

Isotonic solutions may be given subcutaneously, intravenously, and occasionally, intramuscularly.

Use Bacteriostatic Sodium Chloride Injection, USP, 0.9% with due regard for the compatibility of the benzyl alcohol it contains with the particular medicinal substance that is to be dissolved or diluted.

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

HOW SUPPLIED

Bacteriostatic Sodium Chloride Injection, USP, 0.9%, preserved with benzyl alcohol is available as follows:

Product Code	**Unit of Sale**	**Strength**	**Each**

924810	NDC 63323-924-10 Unit of 25	0.9%	NDC 63323-924-01 10 mL Multiple Dose Plastic Vial
924830	NDC 63323-924-30 Unit of 25	0.9%	NDC 63323-924-03 30 mL Multiple Dose Plastic Vial

Use only if solution is clear and seal intact.

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

www.fresenius-kabi.com/us

45765E

Revised: September 2019

PACKAGE LABEL - PRINCIPAL DISPLAY - Bacteriostatic Sodium Chloride 30 mL Multiple Dose Vial Label

NDC 63323-924-03 924830

Bacteriostatic Sodium Chloride Injection, USP

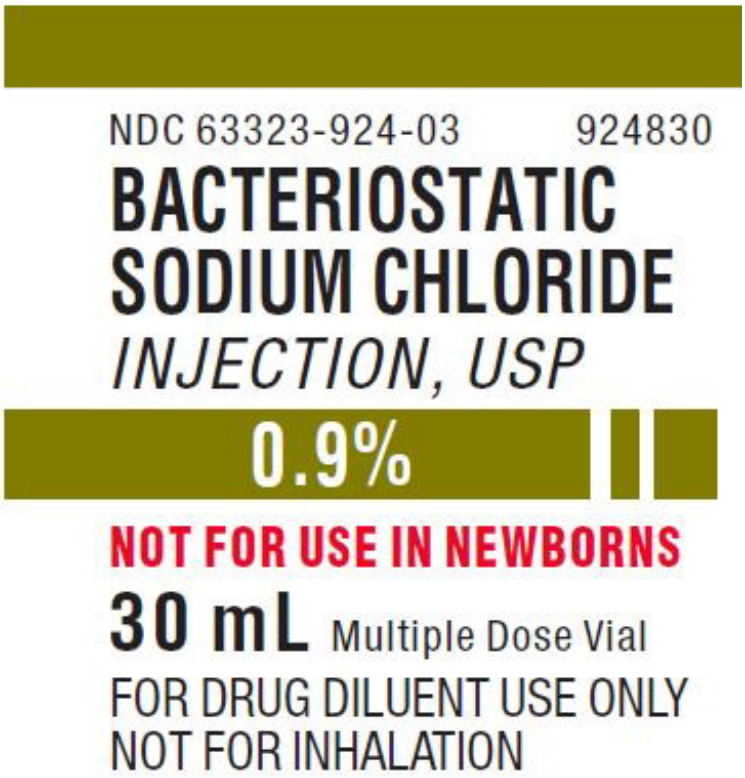
0.9%

NOT FOR USE IN NEWBORNS

30 mL Multiple Dose Vial

For Drug Diluent Use Only

Not for Inhalation



PACKAGE LABEL – PRINCIPAL DISPLAY - Bacteriostatic Sodium Chloride 30 mL Multiple Dose Vial Tray Label

NDC 63323-924-30 924830

Bacteriostatic Sodium Chloride Injection, USP

0.9 %

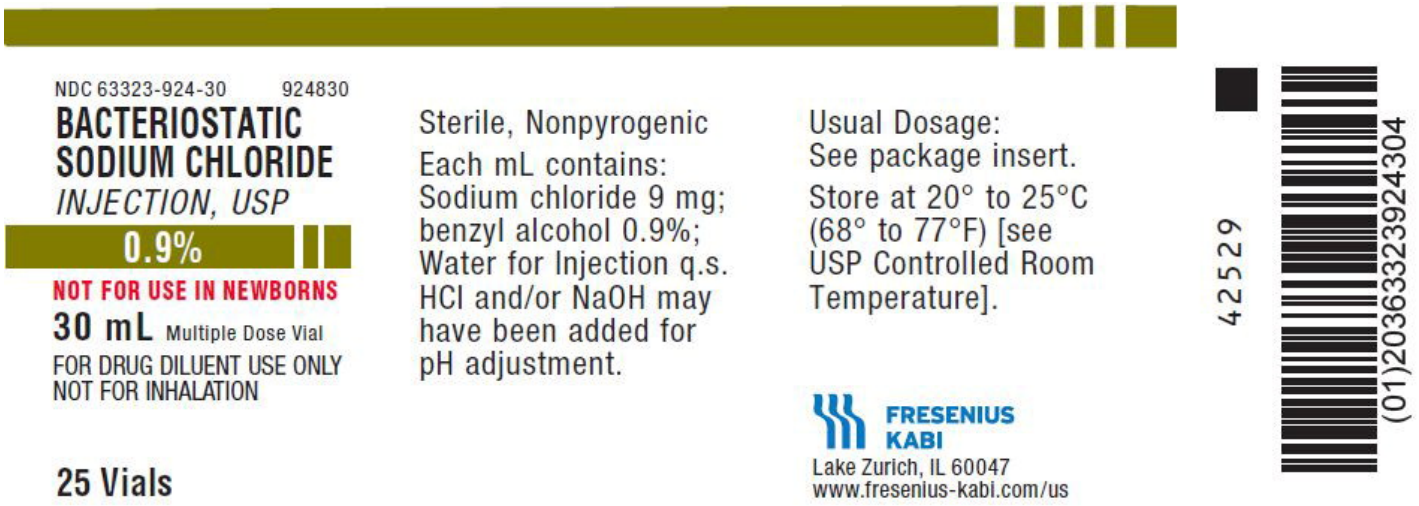
NOT FOR USE IN NEWBORNS

30 mL Multiple Dose Vial

For Drug Diluent Use Only

Not for Inhalation

25 Vials



BACTERIOSTATIC SODIUM CHLORIDE

sodium chloride injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-924
Route of Administration	SUBCUTANEOUS, INTRAVENOUS, INTRAMUSCULAR		

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

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-924-10	25 in 1 TRAY	08/08/2000	
1	NDC:63323-924-01	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:63323-924-30	25 in 1 TRAY	08/08/2000	
2	NDC:63323-924-03	30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088911	08/08/2000	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		840771732	manufacture(63323-924)

Revised: 10/2024 Fresenius Kabi USA, LLC