

BACTERIOSTATIC SODIUM CHLORIDE INJECTION, USP 0.9% Rx Only



DESCRIPTION: Bacteriostatic Sodium Chloride Injection, USP is a sterile, nonpyrogenic, preserved, isotonic solution of 0.9% Sodium Chloride in Water for Injection. Each mL contains: Sodium Chloride 9 mg, Benzyl Alcohol 0.9% as a preservative, Water for Injection q.s. pH (range 4.5 - 7.0) adjusted with Hydrochloric Acid and/or Sodium Hydroxide. It is used as a diluent.

CLINICAL PHARMACOLOGY: 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 and chloride 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 (1.0 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 plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE: Bacteriostatic Sodium Chloride Injection, USP 0.9%, is used for preparing and diluting sterile solutions.

CONTRAINDICATIONS: None known.

WARNINGS: NOT FOR USE IN NEWBORNS. NOT FOR INHALATION.

Benzyl alcohol used as a preservative in Bacteriostatic Sodium Chloride Injection has been associated with toxicity in newborns. Data are unavailable on the toxicity of other preservatives in this age group. Preservative-free Sodium Chloride Injection 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 should be used.

Excessive amounts of Bacteriostatic 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.

Bacteriostatic Sodium Chloride Injection, 0.9% should be used with due regard for the compatibility of the antimicrobial agent or agents it contains with the particular medicinal substance that is to be dissolved or diluted.

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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.

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

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. However, due to potential toxicity of benzyl alcohol in neonates, solutions containing benzyl alcohol are contraindicated in this patient population.

Drug Interactions: Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

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 reexamination if deemed necessary.

OVERDOSE: In the event of overhydration or solute overload, reevaluate the patient and institute appropriate corrective measures. See **WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

DOSAGE AND ADMINISTRATION: The dose should be individualized and is dependent upon the age, weight and clinical condition of the patient.

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 0.9% Benzyl Alcohol, is available as follows:

NDC 0517-0648-25

30 mL Multiple Dose Vials

Packaged in Boxes of 25

Store at controlled room temperature 15°-30°C (59°-86°F) (See USP).

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