APP

45787C/Revised: April 2008

# 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; methylparaben 0.12%; propylparaben 0.012%; 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:**
Bacteriostatic Sodium Chloride Injection, USP, 0.9% should not be used for fluid or sodium chloride replacement.

**WARNINGS:**
Data is unavailable on the toxicity of parabens and other preservatives in newborns. 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. Preservative free Sodium Chloride Injection, USP, 0.9% should be used for flushing intravascular catheters.

**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:**

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.

**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 the bacteriostatic agents.

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 antimicrobial agents 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 parabens is available as follows:

| Product No. | NDC No. | Strength | |
|---|---|---|---|
| 205910 | 63323-259-10 | 0.9% | 10 mL multiple dose vial, in packages of 25. |
| 205930 | 63323-259-30 | 0.9% | 30 mL multiple dose vial, in packages of 25. |

Use only if solution is clear and seal intact.

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

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