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## **STERILE WATER** *FOR INJECTION, USP*

## **BACTERIOSTATIC WATER** *FOR INJECTION, USP*

### **DESCRIPTION:**

These preparations are designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection which contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single dose containers to dilute or dissolve drugs for injection. For IV injection, add sufficient solute to make an approximately isotonic solution. pH 5.0 to 7.0.

Bacteriostatic Water for Injection, USP is a sterile, nonpyrogenic preparation of bacteriostatic water for injection packaged in multiple dose vials. It contains 0.12% methylparaben, 0.012% propylparaben. pH 4.5 to 7.0. **(NOT FOR USE IN NEWBORNS).**

Water for Injection, USP is chemically designated H<sub>2</sub>O.

### **CLINICAL PHARMACOLOGY:**

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 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 (Na<sup>+</sup>) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Sterile Water for Injection, USP or Bacteriostatic Water for Injection, USP when used only as a pharmaceutical aid for diluting or dissolving drugs for parenteral injection, is unlikely to exert a significant effect on fluid balance except possibly in newborns or very small infants.

**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.

**CONTRAINDICATIONS:**

Sterile Water for Injection, USP and Bacteriostatic Water for Injection, USP must be made approximately isotonic prior to use.

Bacteriostatic Water for Injection should not be used in patients with a known sensitivity to the antimicrobial preservative employed.

**WARNINGS:**

Intravenous administration of Sterile Water for Injection or Bacteriostatic Water for Injection without a solute may result in hemolysis.

Methylparaben and propylparaben are the preservatives contained in Bacteriostatic Water for Injection. Data is unavailable on the toxicity of such preservatives in newborns. Where Water for Injection is required for preparing or diluting medications for use in newborns, only preservative-free Sterile Water for Injection should be used.

**PRECAUTIONS:****General**

Do not use for intravenous injection unless the osmolar concentration of additives results in an approximate isotonic admixture.

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection.

Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Do not use Bacteriostatic Water for Injection, USP for those products that specify the use of only Sterile Water for Injection, USP as a sterile solvent.

**Drug Interactions**

Use Bacteriostatic Water for Injection with due regard for the compatibility of the antimicrobial agent it contains with the particular medicinal substance that is to be dissolved or diluted. Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing parabens. Consult with pharmacist, if available.

**Pregnancy Category C**

Animal reproduction studies have not been conducted with Sterile Water for Injection. It is also not known whether Sterile Water for Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection should be given to a pregnant woman only if clearly needed.

Animal reproduction studies have not been conducted with Bacteriostatic Water for Injection. It is also not known whether Bacteriostatic Water for Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bacteriostatic Water for Injection 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. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

### **ADVERSE REACTIONS:**

Reactions which may occur because of this solution, 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.

### **OVERDOSAGE:**

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

### **DOSAGE AND ADMINISTRATION:**

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.

Use aseptic technique for single or multiple entry and withdrawal from all containers.

When diluting or dissolving drugs, mix thoroughly and use promptly.

Do not store reconstituted solutions of drugs for injection unless otherwise directed by the manufacturer of the solute.

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

### **HOW SUPPLIED:**

#### **Sterile Water for Injection, USP**

<b>Product No.</b>	<b>NDC No.</b>	<b>Volume</b>
18505	63323-185-05	5 mL in a 6 mL single-dose vial
185100*	63323-185-00	100 mL in a 100 mL single-dose vial

\*Indicates vial with tear-off seal.

Preservative Free. Discard unused portion.

Packaged in trays of twenty-five.

#### **Bacteriostatic Water for Injection, USP**

**contains parabens**

**(NOT FOR USE IN NEWBORNS):**

<b>Product No.</b>	<b>NDC No.</b>	<b>Volume</b>
24910	63323-249-10	10 mL in a 10 mL multiple-dose vial
24930	63323-249-30	30 mL in a 30 mL multiple-dose vial

Packaged in trays of twenty-five.

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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