

BACTERIOSTATIC WATER- bacteriostatic water injection, solution
REMEDYREPACK INC.

BACTERIOSTATIC WATER Rx only

for Injection, USP

Multiple-dose Vial

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| <p>WARNING: NOT FOR USE IN NEONATES.</p> |
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DESCRIPTION

The following preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

Bacteriostatic Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection containing 0.9% (9 mg/mL) or 1.1% (11 mg/mL) of benzyl alcohol added as a bacteriostatic preservative. It is supplied in a multiple-dose container from which repeated withdrawals may be made to dilute or dissolve drugs for injection. The pH is 5.7 (4.5 to 7.0).

Water for Injection, USP is chemically designated H₂O.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper labeled volume.

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 (1.0 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 (Na⁺) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by 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 very small infants.

INDICATIONS AND USAGE

This parenteral preparation is 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

Due to the potential toxicity of benzyl alcohol in neonates, solutions containing benzyl alcohol must not be used in this patient population.

Parenteral preparations with benzyl alcohol should not be used for fluid replacement.

Parenteral preparations containing benzyl alcohol should not be used in epidural or spinal anesthesia procedures.

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

WARNINGS

Benzyl alcohol, a preservative in Bacteriostatic Water for Injection, USP has been associated with toxicity in neonates. Data are unavailable on the toxicity of other preservatives in this age group. Where water is required for preparing or diluting medications for use in neonates, only preservative-free Sterile Water for Injection should be used.

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

PRECAUTIONS

Do not use Bacteriostatic Water for Injection, USP 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.

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

Pediatric Use

The safety and effectiveness of Bacteriostatic Water for Injection, USP have not been established in pediatric patients. Due to the potential for toxicity, solutions containing benzyl alcohol should not be used in neonates.

Drug Interactions

Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle or in a vehicle containing benzyl alcohol. Consult with pharmacist, if available.

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.

Do not use unless the solution is clear and seal intact.

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, 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 or neonate 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 fluid overload except possibly in 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.

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

Tray of 25

Multiple-dose 30 mL plastic FlipTop vials

NDC: 70518-1236-00

NDC: 70518-1236-01

PACKAGING: 25 in 1 TRAY

PACKAGING: 3 mL in 1 VIAL MULTI DOSE, TYPE 0

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

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

DRUG: Bacteriostatic Water

GENERIC: Bacteriostatic Water

DOSAGE: INJECTION, SOLUTION

ADMINISTRATION: INTRAMUSCULAR

NDC: 70518-1236-0

NDC: 70518-1236-1

PACKAGING: 30 mL in 1 VIAL, MULTI-DOSE

OUTER PACKAGING: 25 in 1 TRAY

ACTIVE INGREDIENT(S):

- WATER 1mL in 1mL

INACTIVE INGREDIENT(S):

- BENZYL ALCOHOL

Bacteriostatic Water

NOT FOR USE IN NEONATES

0.9 % benzyl alcohol added

Injection

QTY: 25 x 30mL Vials

FOR DRUG DILUENT USE ONLY; MultiDose Vials;
Sterile



RX ONLY

NDC #: 70518-1236-00

Expires:

LOT #:

Source NDC: 00409-3977-03

MFG: Hospira, Inc, Lake Forest, IL 60045

Keep this and all medication out of the reach of children



WARNING: Use only if clear and seal is intact and undamaged. Cleanse stopper with antiseptic

Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

Bacteriostatic Water

NOT FOR USE IN NEONATES

0.9% benzyl alcohol added

Injection

QTY: 30 mL Multi-Dose Vial

FOR DRUG DILUENT USE ONLY; Sterile



RX ONLY

NDC #: 70518-1236-01

Expires:

LOT #:

Source NDC: 00409-3977-03

MFG: Hospira, Inc, Lake Forest, IL 60045

Keep this and all medication out of the reach of children

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Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762



BACTERIOSTATIC WATER

bacteriostatic water injection, solution

Product Information

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|-------------------------|--|--------------------|-------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70518-1236(NDC:0409-3977) |
| Route of Administration | INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R) | WATER | 1 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|--------------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | 9 mg in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70518-1236-0 | 25 in 1 TRAY | 06/04/2018 | |
| 1 | NDC:70518-1236-1 | 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 |
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| NDA | NDA018802 | 06/04/2018 | |
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Labeler - REMEDYREPACK INC. (829572556)

Revised: 2/2024

REMEDYREPACK INC.