PRESCRIBING INFORMATION

STERILE WATER FOR INJECTION USP

Liquid, 100%

For Intramuscular, Intravenous, or Subcutaneous Use

Solvents and Diluting Agents (V07AB)

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Sterile Water for Injection USP
Liquid, 100%

DESCRIPTION

Sterile Water for Injection USP is a clear, colourless, odorless liquid. It is sterile, hypotonic, nonpyrogenic, and contains no bacteriostatic or antimicrobial agents. Sterile Water for Injection USP is a diluent or solvent suitable for intramuscular, intravenous or subcutaneous injection after first having been made isotonic by the addition of suitable solute.

pH: 5.5 (5.0 – 7.0).
It is available in single use 10 mL and 50 mL clear USP Type-I glass vials. The stoppers are made of grey chlorobutyl rubber and are latex-free. The vials are available in boxes of 10.

Addition of medication should be accomplished using complete aseptic technique.

ACTION AND CLINICAL PHARMACOLOGY

Sterile Water for Injection USP is used as a diluent or solvent for other parenteral drugs. As such, Sterile Water for Injection USP contributes to the water for hydration when provided in parenteral drug and fluid therapy, after the introduction of suitable additives and/or mixture with suitable solutes to approximate isotonicity.

INDICATIONS AND CLINICAL USE

Sterile Water for Injection USP is indicated for use in adults and pediatric patients as a diluent or solvent in the aseptic preparation of parenteral solutions or as a vehicle for drug administration.

CONTRAINDICATIONS

Sterile Water for Injection USP is a hemolytic agent due to its hypotonicity. Therefore, it is contraindicated for intramuscular, intravenous, or subcutaneous administration without admixing with solute.

WARNINGS

Hypotonic and hemolytic. Do not inject until made isotonic by addition of an appropriate solute, due to the possibility of hemolysis.
The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration.

PRECAUTIONS

General

To minimize the risk of possible incompatibilities arising from the mixing of additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

This solution is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seal are intact.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no data available about the carcinogenicity, mutagenicity, or impairment of fertility of Sterile Water for Injection USP.

Usage in Pregnancy

There are no data available to show the potential for indirect harm to the fetus.

Nursing Mothers

There are no data available to show that Sterile Water for Injection USP can cause harm to infants when injected to nursing mothers.

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.

The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

Overdosage (hypotonic expansion) is a function of an increase in fluid intake over fluid output, and occurs when the increase in the volume of body fluids is due to water alone. Overdosage may occur in patients who receive large quantities of electrolyte-free water to replace abnormal excessive fluid losses, in patients whose renal tolerance to water loads is exceeded, or in patients who retain water postoperatively in response to stress.

Manifestations of water intoxication are behavioral changes (confusion, apathy, disorientation and attendant hyponatremia), central nervous system disturbances (weakness, muscle twitching, headaches, nausea, vomiting, convulsions) and weight gain.

Treatment consists of withholding fluids until excessive water is excreted. In severe hyponatremia it may be necessary to cautiously administer hypertonic saline to increase extracellular osmotic pressure and excretion of excess water by the kidneys.

For management of a suspected drug overdose, contact your regional poison control centre.

DOSAGE AND ADMINISTRATION

This solution is for intramuscular, intravenous or subcutaneous use. Do not inject until made isotonic by addition of appropriate solute.

The dosage and administration of Sterile Water for Injection USP is dependent upon the recommended dosage and administration of the solute used. Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

Some additives may be incompatible. Consult with pharmacist or call the manufacturer at 1-800-363-0584 for any questions or concerns. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

DOSAGE FORMS, COMPOSITION, AND PACKAGING

Sterile Water for Injection USP is supplied sterile and nonpyrogenic in single use 10 mL and 50 mL clear USP Type-I glass vials. The stoppers are made of grey chlorobutyl rubber and are latex-free. The vials are available in boxes of 10.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at 15 – 30°C.

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