FRESENIUS KABI

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STERILE WATER
FOR INJECTION, USP

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

HOW SUPPLIED:

Product Code	Unit of Sale	Volume	Each
918510	NDC 63323-185-10 Unit of 25	10 mL in a 10 mL vial	NDC 63323-185-07 10 mL Single Dose Vial
918520	NDC 63323-185-20 Unit of 25	20 mL in a 20 mL vial	NDC 63323-185-08 20 mL Single Dose Vial
918550	NDC 63323-185-50 Unit of 25	50 mL in a 50 mL vial	NDC 63323-185-09 50 mL Single Dose Vial

Packaged in a plastic vial. Vials are packaged 25 vials per tray.

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

Single dose use. No preservative added. Unused portion of vial should be discarded. Use only if solution is clear and seal intact.

DESCRIPTION:
This preparation is designed solely for parenteral use only after addition to 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 amount to a solute to make an approximately isotonic solution. pH 5.0 to 7.0.

Water for Injection, USP is chemically designated H_2O.

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^+) plays a major role in maintaining physiologic equilibrium.

The small volume of fluid provided by Sterile Water for Injection, USP when used only as a pharmaceutic 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:
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:
Sterile Water for Injection must be made approximately isotonic prior to use.

WARNINGS:
Intravenous administration of Sterile Water for Injection without a solute may result in hemolysis.

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.

Drug Interactions
Some drugs for injection may be incompatible in a given vehicle, or when combined in the same vehicle. 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.

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, 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 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 entry and withdrawal from all containers. Single dose vials should be entered just once.

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.

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