Sterile Water for Injection, USP
25 x 10 mL Single Dose Vials

Shelf Pack: 462-684-00

Contains an antimicrobial or other added substance. Sterile, nonpyrogenic. Use only if clear and seal is intact and unaltered.

Do not give intravenously unless rendered nearly isotonic. Use promptly; discard unused portion.

USE ASEPTIC TECHNIQUE. Remove cover from vial and cleanse stopper with antiseptic.

WITH STERILE SYRINGE AND NEEDLE:
1. Assemble desired portion of vial contents and add to suitable container.
2. Discard any remaining fluid in vial.

Store at 20°C to 25°C (68°F to 77°F)
(See USP Controlled Room Temperature).
DO NOT FREEZE.
Sterile Water for Injection, USP
Rx only

DESCRIPTION
This 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.

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 for 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 neonates 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, USP must be made approximately isotonic prior to use.

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

PRECAUTIONS
Do not use for intravenous injection unless the osmolar concentration of additives results in an appropriate 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.

Pediatric Use
Safety and effectiveness have been established in pediatric patients. However, in neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

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

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.

OVERDOSAGE
Use only as a diluent or solvent. This parenteral preparation is unlikely to pose a threat of fluid overload except possibly in neonates 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.

HOW SUPPLIED
Sterile Water for Injection, USP is supplied in the following:

10 mL single-dose vials packaged in carton of 25 vials (NDC 0641-6147-25)

Storage
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Do NOT FREEZE.

For Product Inquiry call 1-877-845-0689.