STERILE WATER- water injection
Nexus Pharmaceuticals Inc

Sterile Water for Injection, USP

Rx only

Glass Vial

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.

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 intravenous. injection, add sufficient solute to make an approximately isotonic solution.

Water for Injection, USP is chemically designated H_2O.

The glass vial is Type I or II borosilicate glass and meets the requirements of the powdered glass test according to the USP standards.

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 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 Sterile Water for Injection. It is also not known whether sterile water containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile Water for Injection with additives should be given to a pregnant woman only if clearly needed.

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 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. Do not reuse single-dose containers. Discard unused portion.

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 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.

This parenteral should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

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

Unit of Sale	**Total Content**
NDC 14789-131-05 Carton of 25 Single-dose Glass	10 mL
NDC 14789-132-05 Carton of 25 Single-dose Glass	20 mL

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

Manufactured in the USA by
Nexus Pharmaceuticals, LLC.
Lincolnshire, IL 60069
USA

SWIPI01R01
Revised: 07/2023

Principal Display Panel – 10 mL Carton Label

NDC 14789-**131**-05

Rx Only

Sterile Water for Injection, USP

For Drug Diluent Only

WARNINGS: NOT ISOTONIC, HEMOLYTIC

Use only if clear and seal is intact and undamaged

25 x 10 mL Single-dose Vials

NDC 14789-131-05 Rx Only

Sterile Water for Injection, USP

For Drug Diluent Use Only

WARNINGS: NOT ISOTONIC, HEMOLYTIC

Use only if clear and seal is intact and undamaged

25 x 10 mL Single-dose Vials

Contains no antimicrobial or other added substance.

Sterile, nonpyrogenic.

Do not give intravenously unless rendered nearly isotonic.

Use promptly; discard unused portion.

The container closure is not made with natural rubber latex.

NEXUS PHARMACEUTICALS

Manufactured in the USA by:
Nexus Pharmaceuticals, LLC.
Lincolnshire, IL 60069

3 14789 13105 4

NDC 14789-131-05 Rx Only

Sterile Water for Injection, USP

For Drug Diluent Use Only

WARNINGS: NOT ISOTONIC, HEMOLYTIC

Use only if clear and seal is intact and undamaged

25 x 10 mL Single-dose Vials

USE ASEPTIC TECHNIQUE

Remove cover from vial and cleanse stopper with antiseptic

With Sterile Syringe and Needle:

1. Aspirate desired portion of vial contents and add to suitable container
2. Discard any remaining fluid in vial

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

Principal Display Panel – 10 mL Vial Label

NDC 14789-**131**-07

Rx Only

Sterile Water for Injection, USP

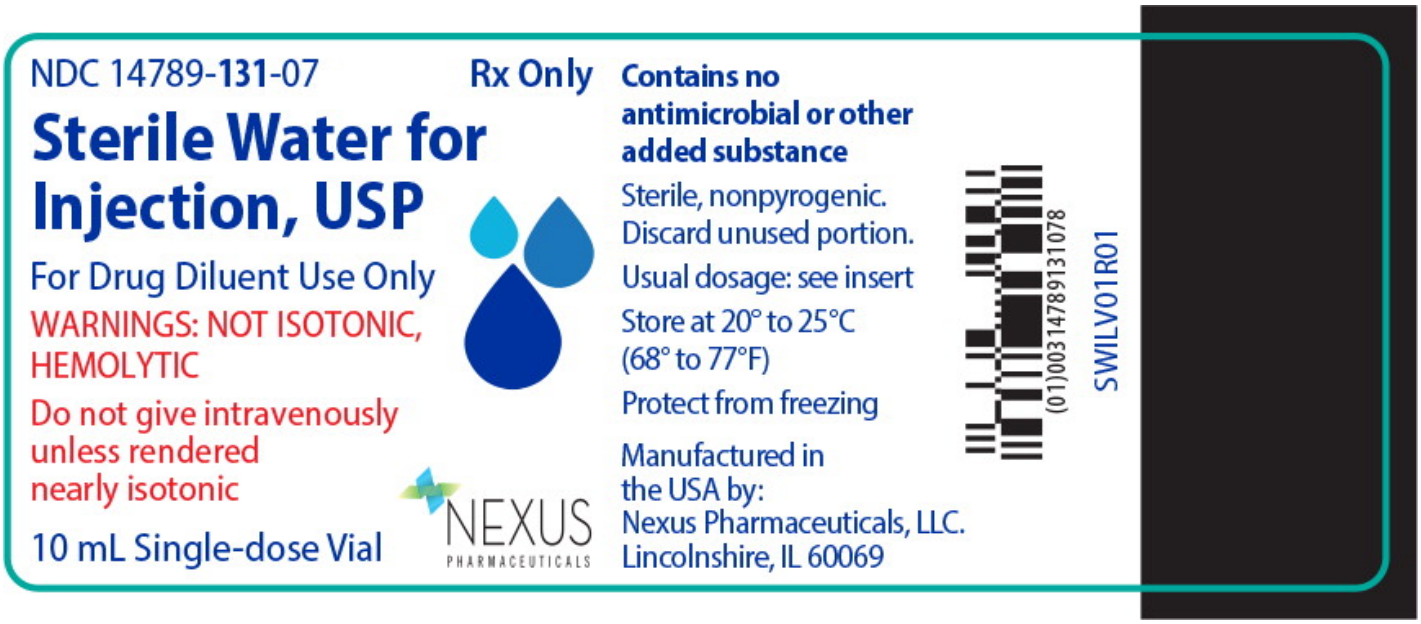
For Drug Diluent Use Only

WARNINGS: NOT ISOTONIC, HEMOLYTIC

Do not give intravenously unless rendered nearly isotonic

10 mL Single-dose Vial

NEXUS PHARMACEUTICALS



Principal Display Panel – 20 mL Carton Label

NDC 14789-**132**-05

Rx Only

Sterile Water for Injection, USP

For Drug Diluent Use Only

WARNINGS: NOT ISOTONIC, HEMOLYTIC

Use only if clear and seal is intact and undamaged

25 x 20 mL Single-dose Vials

Principal Display Panel – 20 mL Vial Label

NDC 14789-**132**-07

Rx Only

Sterile Water for Injection, USP

For Drug Diluent Use Only

WARNINGS: NOT ISOTONIC, HEMOLYTIC

Do not give intravenously unless rendered nearly isotonic

20 mL Single-dose Vial

NEXUS PHARMACEUTICALS

STERILE WATER

water injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14789-131
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	Water	10 mL in 10 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14789-131-05	25 in 1 CARTON	09/25/2023	
1	NDC:14789-131-07	10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217536	09/25/2023	

STERILE WATER

water injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14789-132
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Water (UNII: 059QF0KO0R) (Water - UNII:059QF0KO0R)	Water	20 mL in 20 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14789-132-05	25 in 1 CARTON	09/25/2023	
1	NDC:14789-132-07	20 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217536	09/25/2023	

Labeler - Nexus Pharmaceuticals Inc (620714787)

Establishment

Name	Address	ID/FEI	Business Operations
Nexus Pharmaceuticals Inc		118291262	MANUFACTURE(14789-131, 14789-132)

Establishment

Name	Address	ID/FEI	Business Operations
Nexus Pharmaceuticals Inc		620714787	ANALYSIS(14789-131, 14789-132)