

STERILE WATER- water injection, solution
West-Ward Pharmaceuticals Corp.

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.

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 H₂O.

The glass vial is a Type I borosilicate glass and meets the requirements 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 pharmaceutical 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 Category C

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:

10 mL single dose vials packaged in cartons of 10 vials (NDC 0641-6147-10) and 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.

To report SUSPECTED ADVERSE REACTIONS, contact West-Ward Pharmaceuticals Corp. at 1-877-845-0689, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Manufactured by:

WEST-WARD
A HIKMA COMPANY
Eatontown, NJ 07724 USA

Revised July 2018

462-682-01

PRINCIPAL DISPLAY PANEL

WARNINGS: NOT ISOTONIC. HEMOLYTIC.

NDC 0641-6147-01

Rx only

Sterile Water

for Injection, USP

FOR DRUG DILUENT USE ONLY

10 mL Single Dose Vial

**Contains no antimicrobial
or other added substance.**

Sterile, nonpyrogenic.

**Do not give intravenously
unless rendered nearly
isotonic.**

USUAL DOSAGE: See insert.

Store at 20° to 25°C (68° to 77°F)

[See USP]. DO NOT FREEZE.

WARNINGS: NOT ISOTONIC. HEMOLYTIC.

NDC 0641-6147-01 Rx only

**Sterile Water
for Injection, USP**

FOR DRUG DILUENT USE ONLY

10 mL Single Dose Vial

Contains no antimicrobial
or other added substance.
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**Do not give intravenously
unless rendered nearly
isotonic.**

USUAL DOSAGE: See insert.
Store at 20° to 25°C (68° to 77°F)
[See USP]. DO NOT FREEZE.

Mfd. by: WEST-WARD
Eatontown, NJ 07724 USA
462-683-00

(01)00306416147019

LOT: EXP:

NDC 0641-6147-25

Rx only

Sterile Water

for Injection, USP

FOR DRUG DILUENT USE ONLY

25 x 10 mL Single Dose Vials

Contains no antimicrobial or other added substance.

Sterile, nonpyrogenic. Use only if clear and seal is intact and undamaged.

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. 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].

DO NOT FREEZE.

EXP: LOT: NDC 0641-6147-25 Rx only

**Sterile Water
for Injection, USP**

FOR DRUG DILUENT USE ONLY

25 x 10 mL Single Dose Vials

Mfd. by: WEST-WARD
Eatontown, NJ 07724 USA 462-684-00

Contains no antimicrobial or other added substance.
Sterile, nonpyrogenic. Use only if clear and seal is intact and undamaged.
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. 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].
DO NOT FREEZE.

(01)00306416147255

PRINCIPAL DISPLAY PANEL

NDC 0641-6147-10

Rx only

Sterile Water

for Injection, USP

FOR DRUG DILUENT USE ONLY

10 x 10 mL Single Dose Vials

Contains no antimicrobial or other added substance.

Sterile, nonpyrogenic. Use only if clear and seal is intact and undamaged.

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. 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].
DO NOT FREEZE.

NDC 0641-6147-10 **Rx only** Contains no antimicrobial or other added substance.

Sterile Water for Injection, USP

FOR DRUG DILUENT USE ONLY

10 x 10 mL Single Dose Vials

Mfd. by:  WEST-WARD
Eatontown, NJ 07724 USA

462-788-00



Sterile, nonpyrogenic. Use only if clear and seal is intact and undamaged.
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. 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].
DO NOT FREEZE.

(01)00306416147101

LOT: EXP:

SERIALIZATION IMAGE



GTIN 00301234567896
SN 1234567890123
EXP MMMYYYY
LOT ABCDE12345

STERILE WATER				
water injection, solution				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-6147	
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
WATER (UNII: 059QF0K00R) (WATER - UNII:059QF0K00R)		WATER	1 mL in 1 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-6147-25	25 in 1 CARTON	09/03/2015	
1	NDC:0641-6147-01	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0641-6147-10	10 in 1 CARTON	09/03/2015	

2 | NDC:0641-6147-01 | 10 mL in 1 VIAL; Type 0: Not a Combination Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206369	09/03/2015	

Labeler - West-Ward Pharmaceuticals Corp. (946499746)

Establishment

Name	Address	ID/FEI	Business Operations
Hikma Pharmaceuticals USA Inc.		946499746	ANALYSIS(0641-6147) , LABEL(0641-6147) , MANUFACTURE(0641-6147) , PACK(0641-6147)

Revised: 12/2018

West-Ward Pharmaceuticals Corp.