

**STERILE WATER- water injection, solution**  
**Hikma Pharmaceuticals USA Inc.**

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**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 H<sub>2</sub>O.

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<sup>+</sup>) 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 Hikma Pharmaceuticals USA Inc. at 1-877-845-0689, or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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

## **Manufactured by:**

Hikma Pharmaceuticals USA Inc.

Berkeley Heights, NJ 07922

Revised July 2020

462-682-02

## **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

**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.

462-683-01

Mfd. by Hikma  
Berkeley Heights, NJ 07922

(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

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 Hikma  
Berkeley Heights, NJ 07922

462-684-01  
**hikma.**

**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.

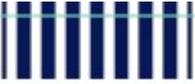
(01)00306416147255




**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

LOT  
EXP.



To open—Cut seal along dotted line.

NDC 0641-6147-10 Rx only Contains no antimicrobial or other added substance.  
Sterile, nongpyrogenic. Use only if clear and seal is intact and undamaged.  
Do not give intravenously unless rendered nearly isotonic. Use promptly; discard unused portion.

**Sterile Water for Injection, USP**

**FOR DRUG DILUENT USE ONLY**

10 x 10 mL Single Dose Vials

Mfd. by Hikma  
Berkeley Heights, NJ 07922  
**hikma.** 462-788-02

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) 033 09 419 147 101

## STERILE WATER

water injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0641-6147
<b>Route of Administration</b>	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>WATER</b> (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	1 mL in 1 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-6147-10	10 in 1 CARTON	09/03/2015	
1	NDC:0641-6147-01	10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0641-6147-25	25 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** - Hikma Pharmaceuticals USA Inc. (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: 4/2024

Hikma Pharmaceuticals USA Inc.