

**STERILE WATER- water injection**  
**Asclemed USA, Inc.**

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**Sterile Water for Injection, USP**

**Rx only**

**Plastic 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 I.V. injection, add sufficient solute to make an approximately isotonic solution.

Water for Injection, USP is chemically designated H<sub>2</sub>O.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper labeled volume.

**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:* 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 76420-082-10 (relabelled from NDC 0409-4887-17) Plastic Fliptop Vials	10 mL

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

### Relabeled by:

Enovachem PHARMACEUTICALS  
Torrance, CA 90501

## PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

Relabeled By:



Sterile Water for Injection, USP

NDC: 76420-082-10

Qty: 10



Distributed By: Hospira, Inc.  
Source NDC: 00409-4887-17  
Description: clear, colorless solution  
Lot #: 00000000 Exp:  
Batch #: 00000000  
Drug Status: RX



(01) 0 0376420 08210 1  
(17)  
(10) 00000000  
(21)

Sterile Water for Injection, USP  
NDC: 76420-082-10  
S/N:  
Qty: 10

Sterile Water for Injection, USP  
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S/N:  
Qty: 10

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NDC: 76420-082-10  
S/N:  
Qty: 10

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

## STERILE WATER

water injection

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:76420-082(NDC:0409-4887)
<b>Route of Administration</b>	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
	NDC:76420-082	10 mL in 1 VIAL, PLASTIC, Type 0; Note Combination		

1	NDC:76420-082-10	10 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product	04/09/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
NDA	NDA018801	06/16/2005		

**Labeler** - Asclemed USA, Inc. (059888437)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-082)

Revised: 1/2021

Asclemed USA, Inc.