

**STERILE WATER- water injection, solution**  
**American Regent, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**STERILE WATER FOR INJECTION, USP**  
**(pH 5.0-7.0)**

**Rx Only**

**NOT FOR DIRECT INJECTION**

**DESCRIPTION:**

Sterile Water for Injection, USP is water for injection sterilized and packaged in single dose vials. It contains no antimicrobial agents or other preservatives. It is used as a diluent. Non-pyrogenic.

**PRECAUTIONS:**

Unused amount should be discarded immediately following withdrawal of any portion of vial contents. Sterile Water for Injection is not isotonic and should not be injected directly into the body.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

**HOW SUPPLIED:**

Sterile Water for Injection, USP

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NDC 0517-3005-25	5 mL Single Dose Vial	Packaged in 25
NDC 0517-3010-25	10 mL Single Dose Vial	Packaged in 25
NDC 0517-3020-25	20 mL Single Dose Vial	Packaged in 25
NDC 0517-3050-25	50 mL Single Dose Vial	Packaged in 25

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**AMERICAN**  
**REGENT, INC.**  
**SHIRLEY, NY 11967**

IN3005

Rev. 1/09

**PRINCIPAL DISPLAY PANEL - 5 mL**

**Contain**

**NDC 0517-3005-01**

**STERILE WATER**  
FOR INJECTION, USP

**5 mL** SINGLE DOSE VIAL  
FOR DRUG DILUENT USE

**Rx Only**

**AMERICAN REGENT, INC.**  
SHIRLEY, NY 11967



**Carton**

**STERILE WATER**  
FOR INJECTION, USP

**NDC 0517-3005-25**  
**25 x 5 mL**  
**SINGLE DOSE VIALS**

**FOR DRUG DILUENT USE**

**Rx Only**

No antimicrobial or other substance has been added. For use as a vehicle, solvent, or diluent for substances to be administered parenterally. Must be made approximately isotonic before intravenous use. Sterile, nonpyrogenic.

**WARNING:** DISCARD UNUSED PORTION.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

Directions for Use: See Package Insert.

**AMERICAN  
REGENT, INC.**  
SHIRLEY, NY 11967

Rev. 11/05

<b>STERILE WATER</b>		<b>NDC 0517-3005-25</b>
FOR INJECTION, USP		<b>25 x 5 mL</b>
		<b>SINGLE DOSE VIALS</b>
<b>FOR DRUG DILUENT USE</b>		<b>Rx Only</b>
No antimicrobial or other substance has been added. For use as a vehicle, solvent, or diluent for substances to be administered parenterally. Must be made approximately isotonic before intravenous use. Sterile, nonpyrogenic.		
<b>WARNING:</b> DISCARD UNUSED PORTION.		
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).		
Directions for Use: See Package Insert.		
AMERICAN REGENT, INC. SHIRLEY, NY 11967		Rev. 11/05
		Lot / Exp.

**PRINCIPAL DISPLAY PANEL - 10 mL**

**Container**

**NDC 0517-3010-01**

**STERILE WATER**  
FOR INJECTION, USP

**10 mL** SINGLE DOSE VIAL

FOR DRUG DILUENT USE

**Rx Only**

**AMERICAN REGENT, INC.**  
SHIRLEY, NY 11967

**NDC 0517-3010-01**  
**STERILE WATER**  
FOR INJECTION, USP

**10 mL**  
SINGLE DOSE VIAL  
FOR DRUG DILUENT  
USE

**Rx Only**

AMERICAN  
REGENT, INC.  
SHIRLEY, NY 11967

Contains no preservatives. Must be made approximately isotonic before intravenous use.

**WARNING: DISCARD UNUSED PORTION.**  
Store at 20° to 25°C (68° to 77°F) (See USP Controlled Room Temperature).  
Directions for Use: See Package Insert.  
Rev. 3/19



Lot / Exp.

**Carton**

**STERILE WATER**  
FOR INJECTION, USP

**NDC 0517-3010-25**  
**25 x 10 mL**  
**SINGLE DOSE VIALS**

**FOR DRUG DILUENT USE**

**Rx Only**

No antimicrobial or other substance has been added. For use as a vehicle, solvent, or diluent for substances to be administered parenterally. Must be made approximately isotonic before intravenous use. Sterile, nonpyrogenic.

**WARNING: DISCARD UNUSED PORTION.**

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

Directions for Use: See Package Insert.

**AMERICAN  
REGENT, INC.**  
SHIRLEY, NY 11967

Rev. 11/05

**STERILE WATER**  
FOR INJECTION, USP

**NDC 0517-3010-25**  
**25 x 10 mL**  
**SINGLE DOSE VIALS**

**FOR DRUG DILUENT USE**

**Rx Only**

No antimicrobial or other substance has been added. For use as a vehicle, solvent, or diluent for substances to be administered parenterally. Must be made approximately isotonic before intravenous use. Sterile, nonpyrogenic.

**WARNING:** DISCARD UNUSED PORTION.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

Directions for Use: See Package Insert.

Rev. 11/05

Lot / Exp.

**AMERICAN  
REGENT, INC.**  
SHIRLEY, NY 11967



**PRINCIPAL DISPLAY PANEL - 20 mL**

**Container**

**NDC 0517-3020-01**

**STERILE WATER**  
FOR INJECTION, USP

**20 mL** SINGLE DOSE VIAL

FOR DRUG DILUENT USE

**Rx Only**

**AMERICAN REGENT, INC.**  
SHIRLEY, NY 11967

**NDC 0517-3020-01**

**STERILE WATER**  
FOR INJECTION, USP

**20 mL** SINGLE DOSE VIAL  
FOR DRUG DILUENT USE

**Rx Only**

AMERICAN  
REGENT, INC.  
SHIRLEY, NY 11967

Contains no preservatives. Must be made approximately isotonic before intravenous use.

**WARNING:** DISCARD UNUSED PORTION.

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

Directions for Use: See Package Insert.

Rev. 3/19



Lot / Exp.

**Carton**

**STERILE WATER**  
FOR INJECTION, USP

**NDC 0517-3020-25**  
**25 x 20 mL**  
**SINGLE DOSE VIALS**

**FOR DRUG DILUENT USE**

**Rx Only**

No antimicrobial or other substance has been added. For use as a vehicle, solvent, or diluent for substances to be administered parenterally. Must be made approximately isotonic before intravenous use. Sterile, nonpyrogenic.

**WARNING:** DISCARD UNUSED PORTION.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

Directions for Use: See Package Insert.

**AMERICAN  
REGENT, INC.**  
SHIRLEY, NY 11967

Rev. 5/18

**STERILE WATER**  
FOR INJECTION, USP

**NDC 0517-3020-25**  
**25 x 20 mL**  
**SINGLE DOSE VIALS**

**FOR DRUG DILUENT USE**

**Rx Only**

No antimicrobial or other substance has been added. For use as a vehicle, solvent, or diluent for substances to be administered parenterally. Must be made approximately isotonic before intravenous use. Sterile, nonpyrogenic.

**WARNING:** DISCARD UNUSED PORTION.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)  
(See USP Controlled Room Temperature).

Directions for Use: See Package Insert.

**AMERICAN  
REGENT, INC.**  
SHIRLEY, NY 11967

Lot / Exp.

Rev. 5/18



**Serialization Label - 5 mL**



LOT 0000

EXP 01/2099

GTIN 00305173005259

SN 0

**Serialization Label - 10 mL**



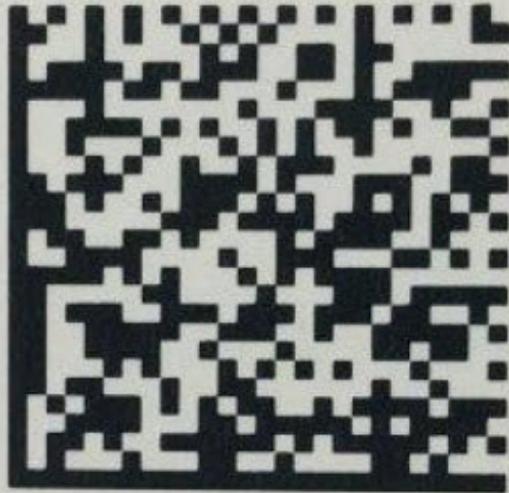
LOT 0000

EXP 01/2099

GTIN 00305173010253

SN 0

**Serialization Label - 20 mL**



LOT 0000

EXP 01/2099

GTIN 00305173020252

SN 0

## STERILE WATER

water injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0517-3005
<b>Route of Administration</b>	INTRAVENOUS		

### 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	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:0517-3005-25	25 in 1 TRAY	09/30/1990	09/30/2021
1	NDC:0517-3005-01	5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/30/1990	09/30/2021

## STERILE WATER

water injection, solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0517-3010
Route of Administration	INTRAVENOUS		

### 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:0517-3010-25	25 in 1 TRAY	04/22/2022	
1	NDC:0517-3010-01	10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/22/2022	

## STERILE WATER

water injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0517-3020	
<b>Route of Administration</b>	INTRAVENOUS			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)		WATER	1 mL in 1 mL	
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0517-3020-25	25 in 1 TRAY	04/22/2022	
1	NDC:0517-3020-01	20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
<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>
unapproved drug other			04/22/2022	

**Labeler** - American Regent, Inc. (002033710)

### Establishment

Name	Address	ID/FEI	Business Operations
American Regent, Inc.		002033710	analysis(0517-3005, 0517-3010, 0517-3020) , manufacture(0517-3005, 0517-3010, 0517-3020)

Revised: 1/2022

American Regent, Inc.