

**STERILE WATER- water irrigant**  
**B. Braun Medical Inc.**

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**Sterile Water for  
Irrigation USP**

**DESCRIPTION**

Sterile Water for Irrigation USP is a sterile, hypotonic, nonpyrogenic irrigating fluid or pharmaceutical aid (solvent) entirely composed of Sterile Water for Injection USP. It is prepared by distillation and contains no antimicrobial or bacteriostatic agents or added buffers. The pH is 5.7 (5.0–7.0)

The plastic container is a copolymer of ethylene and propylene formulated and developed for parenteral drugs. The copolymer contains no plasticizers and exhibits virtually no leachability. The plastic container is also virtually impermeable to vapor transmission and therefore, requires no overwrap to maintain the proper drug concentration. The safety of the plastic container has been confirmed by biological evaluation procedures. The material passes Class VI testing as specified in the U.S. Pharmacopeia for Biological Tests—Plastic Containers. These tests have shown that the container is nontoxic and biologically inert.

The PIC™ Container is PVC-free and DEHP-free.

**CLINICAL PHARMACOLOGY**

Sterile Water for Irrigation USP is utilized for a variety of clinical indications. Because of its low refractive index (1.3325), water provides excellent visibility during endoscopic urological procedures. It is also utilized as a pharmaceutical aid, as well as in the preparation of enteral nutrient products.

Water is hypotonic and will cause hemolysis and will be readily absorbed by the tissues during surgical procedures; therefore, its use under such conditions is not recommended.

**INDICATIONS AND USAGE**

Sterile Water for Irrigation USP is indicated for use as an irrigating fluid or pharmaceutical aid. Sterile Water may also be used as an adjunct in the preparation of non-intravenously administered nutrient mixtures (see **DOSAGE AND ADMINISTRATION**).

**CONTRAINDICATIONS**

Not for injection.

**WARNINGS**

Sterile Water for Irrigation USP is hypotonic and will cause hemolysis, and is not recommended for use during surgical procedures.

After opening container, its contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation.

Discard unused portion of irrigating solution since it contains no preservative.

**PRECAUTIONS**

Use only if solution is clear and container and seal are intact.

## ADVERSE REACTIONS

None known.

## OVERDOSAGE

None known.

## DOSAGE AND ADMINISTRATION

### Irrigation

Use as directed by physician.

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

### Nutrient Mixtures

Sterile Water for Irrigation USP may be used to prepare non-intravenously administered nutrient mixtures. It contains no electrolytes or other added substances. Refer to preparation instructions of particular mixture to be used. The plastic container may be used for administration of non-intravenous nutrient mixture to the patient as appropriate.

## HOW SUPPLIED

Sterile Water for Irrigation USP is supplied sterile and nonpyrogenic in plastic irrigating containers. The 1000 mL and 500 mL containers are packaged 16 per case; the 2000 mL are packaged 8 per case and the 4000 mL are packaged 4 per case.

NDC	Cat. No.	Size
Sterile Water for Irrigation USP (Canada DIN 01963961)		
0264-2101-00	R5000-01	1000 mL
0264-2101-10	R5001-01	500 mL
0264-2101-50	R5005-01	2000 mL
0264-2101-70	R5007	4000 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Do not warm above 150°F (66°C).

Rx only

Revised: March 2009

PIC is a trademark of B. Braun Medical Inc.

## Directions For Use

Aseptic technique is required.

1. Caution – Before use, perform the following checks:

- (a) Read the label. Ensure solution is the one ordered and is within the expiration date.
- (b) Invert container and inspect the solution in good light for cloudiness, haze or particulate matter; check the container for leakage or damage. Any container which is suspect should not be used.

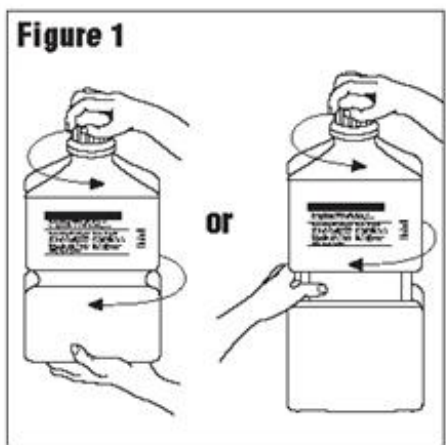
Use only if solution is clear and container and seal are intact.

Single unit container.

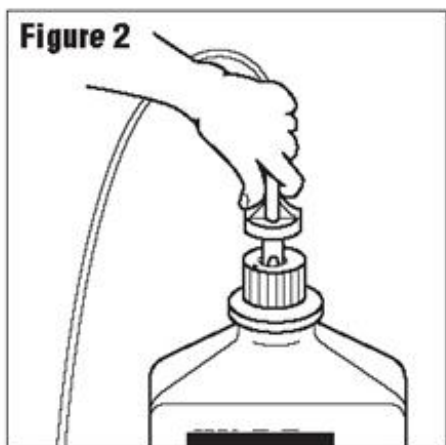
Discard unused portion.

Not for injection.

2. Outer Closure Removal – Grasp the container with one hand and turn the breakaway ring counterclockwise with the other hand until slight resistance is felt. Then, twisting the container in the opposite direction, turn the breakaway ring **sharply** until the entire outer cap is loose and can be lifted off.



3. Connect the administration set through the sterile set port according to set instructions or remove screw cap and pour.



4. Do not warm above 150°F to assure minimal bottle distortion. Keep bottles upright.

**B. Braun Medical Inc.**

Irvine, CA 92614-5895 USA

Made in USA

In Canada, distributed by:

**B. Braun Medical Inc.**

Scarborough, Ontario M1H 2W4

Y36-002-701

**PRINCIPAL DISPLAY PANEL - 1000 mL Container**

**Sterile Water for  
Irrigation USP**

**Warnings: Hypotonic and Hemolytic**

Lot

Exp.

REF R5000-01

NDC 0264-2101-00

DIN 01963961

HK 23675

**1000 mL**

Y37-002-319

No antimicrobial agent or other  
substance has been added.

pH: 5.7 (5.0-7.0)

**Not for Injection.**

See Package Insert.

Use only if solution is clear and  
container and seal are intact.

Sterile, nonpyrogenic. Single unit  
container. Discard unused portion.

**Warning:** Do not warm above  
150°F (66°C).

Recommended Storage:

Room temperature (25°C).

Avoid excessive heat. Protect  
from freezing. See Package Insert.

Rx only

PVC-free and DEHP-free

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# Sterile Water for Irrigation USP

Lot

**Warnings: Hypotonic and Hemolytic**

Exp.

REF R5000-01  
NDC 0264-2101-00

DIN 01963961  
HK 23675

**1000 mL**

Y37-002-319

No antimicrobial agent or other substance has been added.

pH: 5.7 (5.0-7.0)

**Not for Injection.**  
See Package Insert.

Use only if solution is clear and container and seal are intact.

Sterile, nonpyrogenic. Single unit container. Discard unused portion.

**Warning: Do not warm above 150°F (66°C).**

**Recommended Storage:**  
Room temperature (25°C).  
Avoid excessive heat. Protect from freezing. See Package Insert.

Rx only

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**Sterile Water for Irrigation USP**

## PRINCIPAL DISPLAY PANEL - 500 mL Container

### Sterile Water for Irrigation USP

**Warnings: Hypotonic and Hemolytic**

Lot  
Exp.

REF R5001-01  
NDC 0264-2101-10  
DIN 01963961  
HK 23675

**500 mL**

Y37-002-321

No antimicrobial agent or other substance has been added.

pH: 5.7 (5.0-7.0)

**Not for Injection.**

See Package Insert.

Use only if solution is clear and container and seal are intact.

Sterile, nonpyrogenic. Single unit container. Discard unused portion.

**Warning:** Do not warm above 150°F (66°C).

Recommended Storage:

Room temperature (25°C).

Avoid excessive heat. Protect from freezing. See Package Insert.

Rx only

PVC-free and DEHP-free

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<b>Sterile Water for Irrigation USP</b>		Lot
<b>Warnings: Hypotonic and Hemolytic</b>		Exp.
REF R5001-01	DIN 01963961	<b>500 mL</b>
NDC 0264-2101-10	HK 23675	
		Y37-002-321
No antimicrobial agent or other substance has been added.	<b>Warning: Do not warm above 150°F (66°C).</b>	
pH: 5.7 (5.0-7.0)	Recommended Storage: Room temperature (25°C).	
<b>Not for Injection.</b>	Avoid excessive heat. Protect from freezing. See Package Insert.	
See Package Insert.	Rx only	
Use only if solution is clear and container and seal are intact.	PVC-free and DEHP-free	
Sterile, nonpyrogenic. Single unit container. Discard unused portion.		
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<b>Sterile Water for Irrigation USP</b>		

**PRINCIPAL DISPLAY PANEL - 2000 mL Container**

**Sterile Water for Irrigation USP**

**Warnings: Hypotonic and Hemolytic**

Lot  
Exp.

REF R5005-01  
NDC 0264-2101-50  
DIN 01963961  
HK 23675

**2000 mL**

Y37-002-322

No antimicrobial agent or other substance has been added.

pH: 5.7 (5.0-7.0)

**Not for Injection.**  
See Package Insert.

Use only if solution is clear and container and seal are intact.

Sterile, nonpyrogenic. Single unit container. Discard unused portion.

**Warning:** Do not warm above 150°F (66°C).


Recommended Storage:  
Room temperature (25°C).  
Avoid excessive heat. Protect from freezing. See Package Insert.

Rx only

PVC-free and DEHP-free

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<b>Sterile Water for Irrigation USP</b>		Lot
<b>Warnings: Hypotonic and Hemolytic</b>		Exp.
REF R5005-01	DIN 01963961	2000 mL
NDC 0264-2101-50	HK 23675	
		Y37-002-322
No antimicrobial agent or other substance has been added.	<b>Warning:</b> Do not warm above 150°F (66°C).	
pH: 5.7 (5.0-7.0)	Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.	
<b>Not for Injection.</b> See Package Insert.	Rx only	
Use only if solution is clear and container and seal are intact.	PVC-free and DEHP-free	
Sterile, nonpyrogenic. Single unit container. Discard unused portion.		
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<b>Sterile Water for Irrigation USP</b>		



**PRINCIPAL DISPLAY PANEL - 4000 mL Container**

**Sterile Water for  
Irrigation USP**

**Warnings: Hypotonic and Hemolytic**

Lot

Exp.

REF R5007

NDC 0264-2101-70

DIN 01963961

HK 23675

**4000 mL**

Y37-002-351

No antimicrobial agent or other  
substance has been added.

pH: 5.7 (5.0-7.0)

**Not for Injection.**

See Package Insert.

Use only if solution is clear and  
container and seal are intact.

Sterile, nonpyrogenic. Single unit  
container. Discard unused portion.

**Warning:** Do not warm above  
150°F (66°C).

Recommended Storage:

Room temperature (25°C).

Avoid excessive heat. Protect  
from freezing. See Package Insert.

Rx only

PVC-free and DEHP-free

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# Sterile Water for Irrigation USP

Lot

Exp.

**Warnings: Hypotonic and Hemolytic**

REF R5007

DIN 01963961

**4000 mL**

Y37-002-351

NDC 0264-2101-70

HK 23675

No antimicrobial agent or other substance has been added.

Warning: Do not warm above 150°F (66°C).

pH: 5.7 (5.0-7.0)

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

**Not for Injection.**

Rx only

See Package Insert.

Use only if solution is clear and container and seal are intact.

Sterile, nonpyrogenic. Single unit container. Discard unused portion.

PVC-free and DEHP-free

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**Sterile Water for Irrigation USP**



## STERILE WATER

water irrigant

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0264-2101
Route of Administration	IRRIGATION		

### 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:0264-2101-00	16 in 1 CASE	09/10/1970	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

2	NDC:0264-2101-10	16 in 1 CASE	09/10/1970	
2		500 mL in 1 CONTAINER; Type 0: Not a Combination Product		
3	NDC:0264-2101-50	8 in 1 CASE	09/10/1970	
3		2000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
4	NDC:0264-2101-70	4 in 1 CASE	09/10/1970	
4		4000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016734	09/10/1970	

**Labeler** - B. Braun Medical Inc. (002397347)

Revised: 1/2019

B. Braun Medical Inc.