



Sterile Water for Irrigation USP

Sterile Water for Irrigation USP

Indications: For moistening of wound dressings, wound debridement, and device irrigation.

Not for injection. No antimicrobial or other substance added. Sterile, nonpyrogenic, single use. Hypotonic. May cause hemolysis if absorbed systemically.. Discard unused portion.

For Irrigation Only.

PVC-free and DEHP-free

Caution: Warm in oven to not more than 50°C (122°F) for a maximum of 60 days. Do not use unless solution is clear and seal is intact.

Recommended Storage: Room temperature. Avoid excessive heat. Protect from freezing.

Rx Only

Made in USA

Nurse Assist, LLC

4409 Haltom Road, Haltom City, TX 76117

800-649-6800

www.stericaresolutions.com



Sterile Water for Irrigation USP

Initial U.S. 510(k) Approval 2008, Rx Only. Made in the U.S.A.

1 Trade/proprietary name of the device:

Wound Flush, Sterile Water

2 Description of the device:

The Wound Flush, Sterile Water device is a wound and device cleansing solution that is intended for moistening and debriding of dermal wounds and for device irrigation. The solution is sterile water for irrigation and meets all of the associated requirements defined in the USP <31>. The subject device is offered in various bottle sizes with and without a spray applicator.

3 Indications for Use:

Sterile Water is indicated for use as an irrigant.

For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

For Prescription Use:

For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second-degree burns, cuts, abrasions and minor skin irritations and for device irrigations.

4 Technological Characteristics:

The mechanical action of fluid moving across the wound or device provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris.

5 Dosage and Administration

5.1 Important Administration Instructions

For irrigation only. Not for intravenous injection.

Sterile Water is hypotonic with an osmolarity of zero mOsmol/L. It is intended for use as an irrigation fluid and not for intravenous administration or administration by other, parenteral routes (e.g. subcutaneous or intramuscular)

Sterile Water is not potable water and is not intended for oral administration.

Sterile Water that has been warmed must not be returned to storage.

5.2 Recommended Dosage

The volume and/or rate of irrigation depend on the type of procedure and the capacity or the surface area of the area to be irrigated.

5.3 Not for injection:

No antimicrobial or other substance added.

Sterile, nonpyrogenic, single use.

Discard unused portion.

5.4 Hypotonic Solution for Irrigation Only:

PVC-free and

DEHP-free

5.5 Caution:

Osmolarity $\approx$ 0 mOsm/L

Not for injection.

No antimicrobial or other substance added.

Contents sterile unless container is opened or damaged. Do not use unless solution is clear and seal is intact.

Warm in oven to not more than 50°C (122°F) for a maximum of 60 days.

5.6 Recommended Storage:

Room temperature. Avoid excessive heat. Protect from freezing.

6 Preparation and Administration Instructions

6.1 Instructions for Use

Single Use Only

6.2 Warming Recommendations for Nurse Assist Sterile Water Pour Bottles

Nurse Assist Sterile Water Bottles are manufactured in the United States to USP Standards in 100, 250, 500 and 1000mL sizes. The pour bottles incorporate a secure pull tab seal and tamper evident break-band cap closure with foam compression liner to assure sterility. Once opened, the entire contents are to be used and discard unused contents of opened containers, to minimize the potential for bacterial growth and pyrogen formation. Sterile Water does not contain antimicrobial preservatives.

6.2.1 Expiration Two Years based on storage at 24°C (75°F).

Intentional warming of the product should be done in compliance with your facility procedures and requirements.

Warming of Nurse Assist Sterile Water Bottles and method of doing so is entirely to the policy, orders or discretion of the user and equipment to be used.

Nurse Assist has established the following guidelines for users who wish to intentionally warm Nurse Assist bottles:

These bottles have been tested to temperatures not exceeding 50°C (122°F) for a period of no longer than 60 days. Once the plastic bottle container have been warmed for their maximum time-period, (at temperatures not exceeding 50°C), the containers should be removed from the warming device and discarded.

Microwave heating of irrigation fluids is not recommended.

Warm the plastic container in overwrap to near body temperature in a water bath or fluid warmer heated to not more than 45°C.

NOTE: The sterility of the bottle is not affected by the warming instructions above. The contents will remain sterile unless opened or damaged, Nurse Assist conducted testing only at the temperature and time listed above. No extrapolations to other times or temperatures should be made. Bottles can be warmed at a cooler temperature, but the time in the warming oven cannot be exceeded. Bottles should not be returned to the warmer after being removed.

6.2.2 Administration Using the plastic bottle:

Inspect visually for particulate matter and discoloration prior to use. Discard if the fluid is not clear or the seal is broken.

Use aseptic technique.

Remove the pull tab seal and tamper evident break-band cap.

Prevent contact of the fluid with external surface of the container (including the band and cap).

If desired, warm the plastic container in overwrap to near body temperature in a water bath or fluid warmer heated to not more than 50°C for a maximum of 60 days.

7 Contraindications:

There are no known contraindications for Nurse Assist Sterile Water products.

8 Warnings and Precautions

8.1 Hypotonicity

Sterile Water is hypotonic and may cause hemolysis and serious adverse reactions if absorbed systemically.

Serious adverse reactions, including cerebral or pulmonary edema, massive hemolysis, and acute renal failure can result from the hypotonicity of Sterile Water.

8.2 Excessive Water Absorption

Absorption may result in hyponatremia, hypoosmolality, fluid overload, and associated complications including cerebral edema and renal failure.

Monitor patients closely for absorption of clinically relevant amounts of fluid during and for an appropriate period after the procedure. If absorption occurs, discontinue Sterile Water.

Additional close monitoring during and/or after the procedure is recommended for patients at increased risk for developing complications related to hypotonicity, such as:

- fluid overload syndrome, including patients with severe renal impairment, impaired cardiac function, or other clinical conditions associated with edematous states.
- hyponatremic encephalopathy, including pediatric patients; women, in particular premenopausal women; patients with hypoxemia; and patients with underlying central nervous system disease.

Avoid use of Sterile Water in patients with wounds where significant absorption may occur, such as procedures that require irrigation over a longer period of time or an irrigation fluid pressure that promotes absorption (e.g., transurethral resection of prostate). Sterile Water should only be used by clinicians familiar with the treatment of possible complications.

9 Use with Electrosurgery/Cautery

In contrast to other irrigation fluids containing electrolytes, Sterile Water is non-conductive. Therefore, when choosing the distension solution/fluid used with electrosurgery or cautery, ensure compatibility with the equipment.

10 Adverse Reactions

The following adverse reactions have been identified during post approval use of Sterile Water for Irrigation. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Metabolism and Nutrition disorders: Hyponatremia, fluid overload, fluid absorption, electrolyte imbalance.

Nervous System Disorders: Cerebral edema.

General Disorders and Administration Site Conditions: Burning sensation (with irrigation of eyes and skin wounds).

Musculoskeletal and Connective Tissue Disorders: Rhabdomyolysis (myoglobinuria)

Renal and Urinary Disorders: Renal failure.

Other Adverse reactions which may occur in association with absorption of water for irrigation include:

Blood and Lymphatic System Disorders: Hemolysis (hemoglobinemia, hemoglobinuria)

Metabolism and Nutrition Disorders: Hypervolemia, hypoosmolality, hyperkalemia, acid/base balance disorder.

Nervous System Disorders: Encephalopathy (seizure, loss of vision, lethargy, disorientation, irritability, vomiting, nausea, headache).

Cardiac Disorders: Cardiac arrest, cardiac failure, bradycardia, electrocardiogram abnormal.

Vascular Disorders: Hypertension, postoperative hypotension.

Respiratory, Thoracic and Mediastinal Disorders: Respiratory arrest, respiratory failure, pulmonary edema.

11 Use in Specific Populations

11.1 Pregnancy

11.1.1 Risk Summary

Appropriate administration of Sterile Water is not expected to cause harm to a breastfed infant. There is no data on the presence of Sterile Water in either human or animal milk, the effects on the breastfed infant or the effects on milk production. The lack of clinical data during lactation precludes a clear determination of the risk of Sterile Water to a breastfed infant; therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Sterile Water and any potential adverse effects on the breastfed infant from Sterile Water or from the underlying maternal condition.

11.2 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Pediatric patients are at higher risk compared to adults for developing encephalopathy as a complication of hyponatremia, if there is excessive absorption of Sterile Water.

11.3 Geriatric Use

Sterile Water should be used cautiously in older patients. Geriatric patients are more likely to have decreased cardiac, renal, or hepatic function, and other diseases or concomitant drug therapy.

11.4 Overdosage

Excessive rate, volume, pressure or duration of irrigation with hypotonic fluid can result in excessive fluid absorption and permanent morbidity or death as a result of hyponatremia, hypoosmolality and/or

fluid overload. In the event of clinically relevant absorption of Sterile Water, immediate intervention may be required.

11.5 Description

Sterile Water contains water that is sterilized and packaged for use as an irrigant. No antimicrobial agent or other substance has been added. The pH is 5.5 (5.0 to 7.0). Sterile Water is hypotonic with an osmolarity of zero mOsmoVL.

PVC-free and DEHP-free

The plastic container is fabricated from polyethylene. Water in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

The plastic bottle is fabricated from polyethylene. The container requires no vapor barrier.

12 How Supplied/Storage and Handling

Sterile Water is supplied in single use plastic bottles as follows:

Product	Bottle Size
6250	Sterile Water for Irrigation USP 100 mL
6260	Sterile Water for Irrigation USP 250 mL
6390	Sterile Water for Irrigation USP 500 mL
6391	Sterile Water for Irrigation USP 1000 mL
6491	Sterile Water for Irrigation USP 1000 mL

12.1.1 STORAGE

Room temperature. Avoid excessive heat. Protect from freezing. Brief exposure to freezing does not adversely affect the product.

Expiration Two Years based on storage at 24°C (75°F).

13 Patient Information

Inform patients, caregivers, or home healthcare providers of the following risks of Sterile

Water for Irrigation:

- Hypotonicity
- Excessive Water Absorption

14 Labels

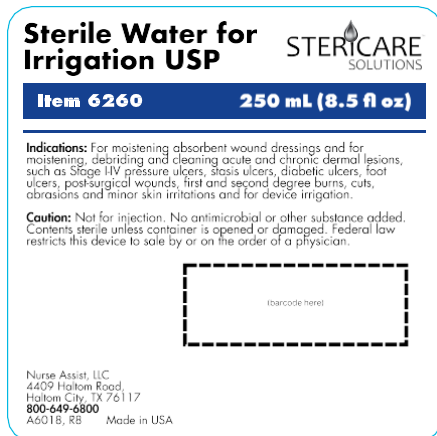
Sterile Water labels are provided for the following references:

Product	Bottle Size
6250	Sterile Water for Irrigation USP 100 mL
6260	Sterile Water for Irrigation USP 250 mL
6390	Sterile Water for Irrigation USP 500 mL
6391	Sterile Water for Irrigation USP 1000 mL
6491	Sterile Water for Irrigation USP 1000 mL

6250 Sterile Water for Irrigation USP 100 mL



6260 Sterile Water for Irrigation USP 250 mL



6390 Sterile Water for Irrigation USP 500 mL

Sterile Water for Irrigation USP



Item 6390
500 mL (16.9 fl oz)

Indications: For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations and for device irrigation.

Caution: Not for injection. No antimicrobial or other substance added. Contents sterile unless container is opened or damaged. Federal law restricts this device to sale by or on the order of a physician.

[GS1-128 barcode and GTIN-HRI here]

Nurse Assist, LLC
4409 Haltom Road,
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800-649-6800
A9047, R2 Made in USA

6391 Sterile Water for Irrigation USP 1000 mL

Sterile Water for Irrigation USP



Item 6391
1000 mL (33.8 fl oz)

Indications: For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations and for device irrigation.

Caution: Not for injection. No antimicrobial or other substance added. Contents sterile unless container is opened or damaged. Federal law restricts this device to sale by or on the order of a physician.

[GS1-128 barcode and GTIN-HRI here]

Nurse Assist, LLC
4409 Haltom Road,
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800-649-6800
A9043, R2 Made in USA

6491 Sterile Water for Irrigation USP 1000 mL

Sterile Water for Irrigation USP



Item 6491
1000 mL (33.8 fl oz)

Indications: For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations and for device irrigation.

Caution: Not for injection. No antimicrobial or other substance added. Contents sterile unless container is opened or damaged. Federal law restricts this device to sale by or on the order of a physician.

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A9051, R2 Made in USA

A9145 R1

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