



0.9% Sodium Chloride for Irrigation USP

0.9% Sodium Chloride 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. Discard unused portion.

Electrolytes (mEq/liter): Sodium 154 Chloride 154 (0.9%w/v)

Isotonic Solution for Irrigation Only. pH: 4.5-7.0

PVC-free and DEHP-free

Osmolarity Calc: 308 mOsmo/liter

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

0.9% Sodium Chloride 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 Normal Saline

2 Description of the device:

The Wound Flush, Sterile Normal Saline 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 saline 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 Normal Saline is indicated for use as an irrigant.

For moistening absorbent wound dressings, wound debridement, and device irrigation.

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 Saline 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 Saline is not potable and is not intended for oral administration.

Sterile Saline 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.

Electrolytes (mEq/liter): Sodium 154 Chloride 154

5.4 Isotonic Solution for Irrigation Only:

pH: 4.5-7.0

PVC-free and DEHP-free

Osmolarity Calc: 308 mOsmo/liter

5.5 Caution:

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 Saline Pour Bottles

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 Normal Saline 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 Normal Saline products.

8 **Warnings and Precautions**

8.1 **Hypersensitivity**

Hypersensitivity reactions to Normal Saline (NS) are rarely reported in literature. Adverse effects of normal saline may occur secondary to the solution or technique of administration. Potential complications include febrile response, infection at the site of injection.

8.2 **Excessive Water Absorption**

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 Normal Saline.

Avoid use of Normal Saline 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).

Normal Saline should only be used by clinicians familiar with the treatment of possible complications.

9 **Use with Electrosurgery/Cautery**

Normal Saline solutions should not be used for irrigation during electrosurgical procedures.

10 **Adverse Reactions**

The following adverse reactions have been identified during post approval use of Normal Saline 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. Hypersensitivity reactions to normal saline (NS) are rarely reported in the

literature. Adverse effects of normal saline may occur secondary to the solution or technique of administration. Potential complications include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

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.

11 Use in Specific Populations

11.1 Pregnancy

11.1.1 Risk Summary

Appropriate administration of Normal Saline is not expected to cause harm to a breastfed infant. There is no data on the presence of Normal Saline 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 Normal Saline a breastfed infant; therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Normal Saline and any potential adverse effects on the breastfed infant from Normal Saline 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 Normal Saline.

11.3 Geriatric Use

Normal Saline 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 volume or pressure of isotonic irrigation fluid may result in fluid overload

11.5 Description

Normal Saline contains water that is sterilized and packaged for use as an irrigant. No antimicrobial agent or other substance has been added. Normal Saline Isotonic Solution for Irrigation Only. pH: 4.5-7.0

PVC-free and DEHP-free Osmolarity Calc: 308 mOsmo/liter.

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

Normal Saline is supplied in single use plastic bottles as follows:

Product	Bottle Size
6240	0.9% Sodium Chloride Irrigation USP 100 mL
6270	0.9% Sodium Chloride Irrigation USP 250 mL
6380	0.9% Sodium Chloride Irrigation USP 500 mL
6381	0.9% Sodium Chloride Irrigation USP 1000 mL
6481	0.9% Sodium Chloride 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 Normal Saline for Irrigation:

- Hypotonicity
- Excessive Water Absorption

14 Labels

Normal Saline labels are provided for the following references:

Product	Bottle Size
6240	0.9% Sodium Chloride Irrigation USP 100 mL
6270	0.9% Sodium Chloride Irrigation USP 250 mL
6380	0.9% Sodium Chloride Irrigation USP 500 mL
6381	0.9% Sodium Chloride Irrigation USP 1000 mL
6481	0.9% Sodium Chloride Irrigation USP 1000 mL

6240 0.9% Sodium Chloride Irrigation USP 100 mL

0.9% Sodium Chloride Irrigation USP **STERICARE SOLUTIONS**

Item 6240 100 mL (3.4 fl oz)

Indications: For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage 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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800-649-6800
A6016, R9 Made in USA



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6270 0.9% Sodium Chloride Irrigation USP 250 mL

0.9% Sodium Chloride Irrigation USP **STERICARE SOLUTIONS**

Item 6270 250 mL (8.5 fl oz)

Indications: For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage 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.

(barcode here)

Nurse Assist, LLC
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Haltom City, TX 76117
800-649-6800
A6017, R9 Made in USA

6380 0.9% Sodium Chloride Irrigation USP 500 mL

0.9% Sodium Chloride Irrigation USP **STERICARE SOLUTIONS**

Item 6380 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 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.

(352-128 barcode and GTIN HRI: here)

Nurse Assist, LLC
4409 Haltom Road
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800-649-6800
A9046, R2 Made in USA

A9416, R1

SteriCare Solutions
4409 Haltom Road
Haltom City, TX 76117

Toll Free: 800-649-6800
Web: www.stericaresolutions.com

6381 0.9% Sodium Chloride Irrigation USP 1000 mL

**0.9% Sodium Chloride
Irrigation USP**



Item 6381
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
Haltom City, TX 76117
800-649-6800
A9042, R2 Made in USA

6481 0.9% Sodium Chloride Irrigation USP 1000 mL

**0.9% Sodium Chloride
Irrigation USP**



Item 6481
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
A9050, R1 Made in USA

A9416, R1

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