

**STERILE WATER FOR IRRIGATION- sterile water for irrigation,
solution irrigant
Laboratorios Alfa SRL**

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.

DESCRIPTION

Disclaimer: This product is intended for veterinary use only. It is manufactured in accordance with current good manufacturing practices (cGMP) and meets recognized standards for sterility and quality. This product is marketed as an unapproved veterinary drug in accordance with applicable regulations.

Sterile Water for Irrigation | For Animal Use Only | Sterile-Non-pyrogenic

ROUTE OF ADMINISTRATION: For irrigation only. Not for injection.

DESCRIPTION:

Sterile Water for Irrigation, USP is a sterile, nonpyrogenic, hypotonic solution intended for irrigation use in animals. It contains no antimicrobial agents, bacteriostatic agents, or added buffers. The solution is prepared by distillation and is intended for irrigation only. It functions as an irrigating fluid for cleansing body cavities, tissues, wounds, and surgical sites during diagnostic and operative procedures. Composition and pH range are shown in Table 1.

Table 1: **Veterinary Sterile Water 100% for Irrigation, USP**

Size (mL)	Composition (mg/100 mL)	
	Sterile Water	pH
100		
250		
500	100%	5.0-7.0
1000		

The plastic container, a semi-rigid bottle is made of Clear Polypropylene (PP) bottle with printed product label, with white/red plastic cap, safety strap and liner. Packed in corrugated boxes, identified with a white label with the corresponding information.

OTHER SAFETY INFORMATION

CAUTION: Federal law (USA) restricts this drug to use by or on the order of a licensed veterinarian.

CLINICAL PHARMACOLOGY (Veterinary use):

Sterile Water for Irrigation, USP, is a sterile, nonpyrogenic, hypotonic solution

intended for irrigation of body cavities, tissues, wounds, and surgical sites in animals. Its primary action is mechanical cleansing, aiding in the removal of debris, blood, and contaminants during diagnostic or surgical procedures. It may also serve as a diluent or vehicle for compatible veterinary drugs intended for irrigation. Because the solution is hypotonic and solute-free, systemic absorption of large volumes can lead to electrolyte disturbances; therefore, care should be taken to minimize absorption during use.

INDICATIONS AND USAGE

- **Sterile Water for Irrigation, USP**, is indicated for use as an irrigating fluid for washing, rinsing, and dilution procedures in animals where the use of a sterile, nonpyrogenic, solute-free solution is appropriate. **For irrigation only. Not for injection. For veterinary use only.**

CONTRAINDICATIONS

- **Sterile Water for Irrigation, USP is not for injection.**

WARNINGS:

- Sterile Water for Irrigation, USP is hypotonic and may cause hemolysis. It is not recommended for use during surgical procedures. Single-use container. Discard any unused portion promptly after opening to minimize the risk of contamination or pyrogen formation. Inspect solution before use. See Instructions for Use. The container label bears the statement: This solution is hemolytic and may cause hemolysis. See package insert for complete warnings. Keep out of the reach of children

PRECAUTIONS

- Inspect solution before use. See Instructions for Use.
- To minimize the risk of incompatibilities when mixing with additives, inspect the final solution for cloudiness or precipitation immediately after mixing, before administration, and periodically during use.
- Do not use if the product is expired, the lot number is missing or illegible.
- Maintain aseptic conditions

USE IN PREGNANT OR LACTATING ANIMALS:

The safety of Sterile Water for Irrigation, USP has not been established in pregnant or lactating animals. Use only when the potential benefits justify the potential risks. Veterinarian discretion is advised. A documented risk-benefit assessment is recommended.

ADVERSE EVENT REPORTING

To report suspected adverse reactions, contact Vedco Inc. at (888) 708-3326 or report to the FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae

ADVERSE REACTIONS

If an adverse reaction does occur, discontinue the irrigation, evaluate the patient,

institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary. Reported adverse reactions include: Hemolysis due to hypotonicity. Hyponatremia and associated neurological symptoms. Neurological signs such as tremors or seizures may occur secondary to hyponatremia. Fluid overload leading to pulmonary edema.

OVERDOSAGE

Excessive absorption of Sterile Water for Irrigation, USP, particularly when used under pressure or in large volumes, may result in water intoxication, hyponatremia, hypoosmolality, and fluid overload. Clinical signs may include lethargy, weakness, ataxia, altered mentation, tremors, seizures, or respiratory distress. In severe cases, coma or death may occur. If clinically significant absorption is suspected, discontinue irrigation immediately and initiate appropriate corrective measures such as electrolyte monitoring, fluid restriction, and supportive care. Monitor serum electrolytes, fluid balance, and provide supportive care. In severe cases, consider diuretics, dialysis or other interventions as directed by a veterinarian. [see Warnings and Precautions for additional information]

DOSAGE AND ADMINISTRATION

- This is a **single-use container**. See **Instructions for Use** for inspection guidelines.
- **Use only as directed by a veterinarian**. Typical irrigation volumes range from 50 mL to 1000 mL depending on the size of the cavity or wound and the nature of the procedure.
- Inspect the solution visually for particulate matter and discoloration prior to administration, whenever solution and container permit
- The dose is dependent upon the capacity or surface area of the structure to be irrigated and the nature of the procedure. When used as a diluent or vehicle for drugs, the manufacturer's recommendations should be followed
- Administer slowly and avoid excessive pressure to minimize the risk of fluid absorption
- Aseptic technique must be used throughout handling and administration
- If additives are introduced, use aseptic technique and mix thoroughly
- **Do not store any solution containing additives**. See **Shelf Life** for disposal instructions.

HOW SUPPLIED

Sterile water for irrigation, USP solution is available in the following sizes:

BOTTLES

NDC#

Sterile Water for irrigation, 1000 mL

NDC 72483-208-02

Sterile Water for irrigation, 500 mL

NDC 72483-208-01

INSTRUCTIONS FOR USE:

PLASTIC BOTTLE:

NOTE: Before use, perform the following checks:

- Read the label. Verify the solution composition, lot number, and expiration date on the container.
- Do not use if the product is expired, the lot number is missing or illegible, or if the solution is cloudy or contains a precipitate.
- Invert the container and inspect in good light for leaks or particulate matter. If leaks are found or the seal is not intact, discard the solution.
- **Use only if the solution is clear and the container and seals are intact.**

PREPARATION FOR ADMINISTRATION:

1. Use aseptic technique when preparing and handling the container.
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.
3. 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.
4. Remove screw cap and pour.
5. Once opened, use immediately and discard any unused portion.

INTRODUCTION OF ADDITIVES:

Warning: Some additives may be incompatible.

Known incompatible additives include:

- Strong oxidizing agents
- Alcohol-containing solutions
- Solutions with high electrolyte concentrations

Always verify compatibility before mixing. If incompatibility is suspected, do not use the mixture.

To Add Medication Before Solution Administration.

1. If additives are introduced, follow aseptic technique as described above.
2. Mix solution and medication thoroughly before use.

NOTE: See full directions accompanying the administration set.

STORAGE

- Store at a temperature not higher than 30°C (86°F). Avoid excessive heat. Protect from freezing.

CAUTION: Federal law (USA) restricts this drug to use by or on the order of a licensed veterinarian

Manufactured by:

LABORATORIOS ALFA S.R.L

Santo Domingo, Dominican Republic

www.laboratoriosalfa.com

+1-809-544-0222

Toll Free: +1-800-969-0581

Made in Dominican Republic

PACKAGE INSERT

For Animal Use Only

ALFA VETERINARY STERILE WATER FOR IRRIGATION, USP
Sterile Water Irrigant, solution
Laboratorios ALFA



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Sterile Water for Irrigation | For Animal Use Only | Sterile-Non-pyrogenic

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- For irrigation only. Not for injection.

DESCRIPTION:

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Table 1: **Veterinary Sterile Water 100% for Irrigation, USP**

Size (mL)	Composition (mg/100 mL)	pH
	Sterile Water, USP (H ₂ O)	
100	100%	5.0 – 7.0
250		
500		
1000		

- The **plastic container**, a semi-rigid bottle is made of Clear Polypropylene (PP) bottle with printed product label, with white/red plastic cap, safety strap and liner. Packed in corrugated boxes, identified with a white label with the corresponding information.

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ALFA VETERINARY STERILE WATER FOR IRRIGATION, USP

Sterile Water Irrigant, *solution*

Laboratorios ALFA



INDICATIONS AND USAGE:

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CONTRAINDICATIONS:

- **Sterile Water for Irrigation, USP** is not for injection.

WARNINGS:

- **Sterile Water for Irrigation, USP** is hypotonic and may cause hemolysis. It is not recommended for use during surgical procedures.
- **Single-use container. Discard any unused portion promptly after opening** to minimize the risk of contamination or pyrogen formation
- Inspect solution before use. See **Instructions for Use**.

The container label bears the statement:

- This solution is hemolytic and may cause hemolysis. See package insert for complete warnings
- **Keep out of the reach of children**

PRECAUTIONS:

- Inspect solution before use. See **Instructions for Use**.
- To minimize the risk of incompatibilities when mixing with additives, inspect the final solution for cloudiness or precipitation immediately after mixing, before administration, and periodically during use.
- Do not use if the product is expired, the lot number is missing or illegible.
- Maintain aseptic conditions

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ADVERSE REACTIONS:

- If an adverse reaction does occur, discontinue the irrigation, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.
- Reported adverse reactions include:
 - Hemolysis due to hypotonicity
 - Hyponatremia and associated neurological symptoms
 - Neurological signs such as tremors or seizures may occur secondary to hyponatremia
 - Fluid overload leading to pulmonary edema

OVERDOSAGE:

- Excessive absorption of **Sterile Water for Irrigation, USP**, particularly when used under pressure or in large volumes, may result in water intoxication, hyponatremia, hypoosmolality, and fluid overload. Clinical signs may include lethargy, weakness, ataxia, altered mentation, tremors, seizures, or respiratory distress. In severe cases, coma or death may occur. If clinically significant absorption is suspected, discontinue irrigation immediately and initiate appropriate corrective measures such as electrolyte monitoring, fluid restriction, and supportive care. Monitor serum electrolytes, fluid balance, and provide supportive care. In severe cases, consider diuretics, dialysis or other interventions as directed by a veterinarian. [see **Warnings and Precautions for additional information**]

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- The dose is dependent upon the capacity or surface area of the structure to be irrigated and the nature of the procedure. When used as a diluent or vehicle for drugs, the manufacturer's recommendations should be followed
- Administer slowly and avoid excessive pressure to minimize the risk of fluid absorption
- Aseptic technique must be used throughout handling and administration
- If additives are introduced, use aseptic technique and mix thoroughly
- **Do not store any solution containing additives**. See **Shelf Life** for disposal instructions.

HOW SUPPLIED:

Sterile water for irrigation, USP solution is available in the following sizes:



BOTTLES

Sterile Water for irrigation, 1000 mL
Sterile Water for irrigation, 500 mL

NDC#

72483-208-02
72483-208-01



INSTRUCTIONS FOR USE:

PLASTIC BOTTLE:

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- Invert the container and inspect in good light for leaks or particulate matter. If leaks are found or the seal is not intact, discard the solution.
- **Use only if the solution is clear and the container and seals are intact.**

PREPARATION FOR ADMINISTRATION:

1. Use aseptic technique when preparing and handling the container.
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.
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4. Remove screw cap and pour.
5. Once opened, use immediately and discard any unused portion.

INTRODUCTION OF ADDITIVES:

Warning: Some additives may be incompatible.

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To Add Medication Before Solution Administration.

1. If additives are introduced, follow aseptic technique as described above.
2. Mix solution and medication thoroughly before use.

NOTE: See full directions accompanying the administration set.

STORAGE:

Store at a temperature not higher than 30°C (86°F).
Avoid excessive heat. Protect from freezing.

ALFA VETERINARY STERILE WATER FOR IRRIGATION, USP
Sterile Water Irrigant, *solution*
Laboratorios ALFA



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For Veterinary Use Only

Sterile Water for Irrigation, 500 mL NDC 72483-208-01

Sterile Water for Irrigation, 1000 mL NDC 72483-208-02

NDC 72483-208-01



500 mL

STERILE WATER FOR IRRIGATION, USP

Not for injection • For irrigation only • Sterile, nonpyrogenic

FOR VETERINARY USE ONLY

Prepared by distillation. **Each mL contains:** Sterile Water 100% for Irrigation, USP; **pH:** 5.0–7.0 (approximate); **Osmolarity:** 0 mOsm/L (hypotonic).

No antimicrobial agent or other substances have been added.

WARNINGS: FOR IRRIGATION ONLY. NOT FOR INJECTION. This solution is not isotonic and is hemolytic. See package insert for complete warnings. May cause hemolysis if absorbed systemically.

PRECAUTIONS: Use only if solution is clear and container and seal are intact. **Single-use container. Discard unused portion.**

Avoid prolonged or high-pressure irrigation.

DOSAGE AND ADMINISTRATION: As directed by a veterinarian.

STORAGE: Store at a temperature not higher than 30°C (86°F).

Avoid excessive heat. Protect from freezing.

Keep out of Reach of Children.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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1-800-969-0581 / www.laboratoriosalfa.com
Made in Dominican Republic

Lot.:

Exp.:



NDC 72483-208-02



1000 mL

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Lot:
Exp:

STERILE WATER FOR IRRIGATION

sterile water for irrigation, solution irrigant

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:72483-208
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (AQUA - UNII:059QF0KO0R)	WATER	100 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72483-208-01	500 mL in 1 BOTTLE, PLASTIC		
2	NDC:72483-208-02	1000 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/09/2025	

Labeler - Laboratorios Alfa SRL (815941244)

Revised: 1/2026

Laboratorios Alfa SRL