

ALFA VETERINARY 0.9% SODIUM CHLORIDE- sodium chloride, 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.

Sodium Chloride 0.9% for Irrigation | For Veterinary Use Only | Sterile-Non-pyrogenic

ROUTE OF ADMINISTRATION: For irrigation only

DESCRIPTION:

Active Ingredient: Sodium Chloride 0.9%

Vehicle: Water for Irrigation

Sodium Chloride 0.9% for Irrigation, USP is a sterile, nonpyrogenic solution supplied in a single-use container 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, osmolarity, and pH are provided in Table 1.

Table 1. **Sodium Chloride for Irrigation 0.9% Irrigation, USP**

Size (mL)	Composition (mg/100 mL)		pH	Concentration (mEq/L)		Caloric Content (kcal/L)
	Sodium Chloride, USP (NaCl)	*Osmolarity (mOsmol/L)(Calculated)		Sodium Chloride		
500	900	308	4.5-	154	154	0
1000			7.0			

The plastic container, a semi-rigid bottle is made of clear polypropylene (PP) 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):

Sodium Chloride 0.9% Irrigation, USP is sterile, nonpyrogenic and isotonic solution with an osmolarity of approximately 308 mOsmol/L. It is physiologically compatible with animal tissues and is intended for irrigation of body cavities, tissues, and surgical sites. The solution contains no antimicrobial agents or preservatives.

INDICATIONS AND USAGE:

- **Sodium Chloride 0.9% Irrigation, USP** is indicated for irrigation of body cavities, tissues, wounds, and surgical sites in animals to cleanse, flush, or moisten during diagnostic and operative procedures.
- **For irrigation only. Noto for injection. Not for parenteral administration.**

CONTRAINDICATIONS:

Do not use for injection or parenteral administration. Do not use during electrosurgical procedures due to the risk of electrical conduction. • Do not use in animals with known hypersensitivity to sodium chloride.

WARNINGS:

- **For irrigation only. Not for injection or parenteral administration.**
- See **Instructions for Use** for inspection guidelines.
- Large volumes of irrigation fluid may be absorbed systemically, which can lead to fluid and/or solute overload, dilution of serum electrolytes, overhydration, congested states, or pulmonary edema
- When used as a diluent, verify compatibility with additives
- The risk of dilutional states is inversely proportional to electrolyte concentration; the risk of solute overload is directly proportional to electrolyte concentration
- Avoid use during electrosurgical procedures due to potential electrical conduction risks
- **Single-use container. Discard any unused portion promptly after opening** to minimize the risk of contamination or pyrogen formation.

The container label bears the statement:

- See package insert for complete warnings
- **Keep out of the reach of children**

PRECAUTIONS:

- Inspect solution before use. See Instructions for Use.
- Use with caution in animals with cardiac or renal impairment, or in those predisposed to fluid overload, as systemic absorption of irrigation fluid may occur
- Monitor for signs of overhydration, electrolyte imbalance, or congestive states, especially when large volumes are used or in small or compromised animals
- 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 Sodium Chloride 0.9% for Irrigation, USP has not been established in pregnant or lactating animals. Use only when the potential benefits justify the potential risks to the fetus or neonate. 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 occurs, discontinue irrigation immediately, evaluate the animal, and initiate appropriate veterinary treatment. Retain the remainder of the solution for examination if necessary. • Reported adverse reactions include: · Febrile response, · Infection at the site of irrigation, · Local irritation, · Extravasation, · Systemic effects such as hypervolemia if large volumes are absorbed

OVERDOSAGE:

• In cases of overhydration or solute overload due to systemic absorption of irrigation fluid, discontinue use immediately, reassess the animal's clinical status, and implement appropriate corrective measures. **[See Warnings, 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.** The volume used depends on the size of the animal, the area to be irrigated, and the clinical situation.
- Avoid excessive pressure during irrigation to prevent tissue damage and minimize systemic 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:

Veterinary Sodium Chloride 0.9% for Irrigation, USP solution is available in the following sizes:

BOTTLES

NDC#

Sodium chloride 0.9% for Irrigation, 500 mL NDC 72483-207-01

Sodium chloride 0.9% for Irrigation, 1000 mL NDC 72483-207-02

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 seal 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.

STORAGE:

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

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

Manufactured by:

LABORATORIOS ALFA S.R.L

Santo Domingo, Dominican Republic

www.laboratoriosalfa.com

Toll Free: +1-800-969-0581

Made in Dominican Republic

PACKAGE INSERT

For Animal Use Only

ALFA VETERINARY SODIUM CHLORIDE 0.9% FOR IRRIGATION, USP
Sodium Chloride 0.9% Irrigant, solution
Laboratorios ALFA



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Sodium Chloride 0.9% for Irrigation | For Veterinary Use Only | Sterile-Non-pyrogenic

ROUTE OF ADMINISTRATION:

- For irrigation only. Not for injection.

DESCRIPTION:

Active Ingredient: Sodium Chloride 0.9%

Vehicle: Water for Irrigation

Sodium Chloride 0.9% for Irrigation, USP is a sterile, nonpyrogenic solution supplied in a single-use container 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, osmolarity, and pH are provided in Table 1.

Table 1. **Sodium Chloride 0.9% Irrigation, USP**

Size (mL)	Composition (mg/100 mL)	*Osmolarity (mOsmol/L) (Calculated)	pH	Concentration (mEq/L)		Caloric Content (kcal/L)
	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
500	900	308	4.5-7.0	154	154	0
1000						

- The plastic container, a semi-rigid bottle is made of clear polypropylene (PP) 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.



CLINICAL PHARMACOLOGY (Veterinary use):

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CONTRAINDICATIONS:

- Do not use for injection or parenteral administration.
- Do not use during electrosurgical procedures due to the risk of electrical conduction.
- Do not use in animals with known hypersensitivity to sodium chloride.

WARNINGS:

- **For irrigation only. Not for injection or parenteral administration.**
- See **Instructions for Use** for inspection guidelines.
- Large volumes of irrigation fluid may be absorbed systemically, which can lead to fluid and/or solute overload, dilution of serum electrolytes, overhydration, congested states, or pulmonary edema
- When used as a diluent, verify compatibility with additives
- The risk of dilutional states is inversely proportional to electrolyte concentration; the risk of solute overload is directly proportional to electrolyte concentration
- Avoid use during electrosurgical procedures due to potential electrical conduction risks
- **Single-use container. Discard any unused portion promptly after opening** to minimize the risk of contamination or pyrogen formation.

The container label bears the statement:

- See package insert for complete warnings
- **Keep out of the reach of children**

PRECAUTIONS:

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- Use with caution in animals with cardiac or renal impairment, or in those predisposed to fluid overload, as systemic absorption of irrigation fluid may occur
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- Maintain aseptic conditions

ALFA VETERINARY SODIUM CHLORIDE 0.9% FOR IRRIGATION, USP
Sodium Chloride 0.9% Irrigant, solution
Laboratorios ALFA



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ADVERSE EVENT REPORTING

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ADVERSE REACTIONS:

- If an adverse reaction occurs, discontinue irrigation immediately, evaluate the animal, and initiate appropriate veterinary treatment. Retain the remainder of the solution for examination if necessary
- Reported adverse reactions include:
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 - Systemic effects such as hypervolemia if large volumes are absorbed

OVERDOSAGE:

- In cases of overhydration or solute overload due to systemic absorption of irrigation fluid, discontinue use immediately, reassess the animal's clinical status, and implement appropriate corrective measures. [See **Warnings, Precautions for additional information**]

DOSAGE AND ADMINISTRATION:

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- Avoid excessive pressure during irrigation to prevent tissue damage and minimize systemic 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:

Veterinary Sodium Chloride 0.9% for Irrigation, USP solution is available in the following sizes:

BOTTLES

Sodium chloride 0.9% for irrigation, 1000 mL
Sodium chloride 0.9% for irrigation, 500 mL

NDC#

72483-207-02
72483-207-01

ALFA VETERINARY SODIUM CHLORIDE 0.9% FOR IRRIGATION, USP
Sodium Chloride 0.9% Irrigant, solution
Laboratorios ALFA



INSTRUCTIONS FOR USE:

PLASTIC BOTTLE

NOTE: Before use, perform the following checks:

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4. Remove screw cap and pour.
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STORAGE:

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

ALFA VETERINARY SODIUM CHLORIDE 0.9% FOR IRRIGATION, USP

Sodium Chloride 0.9% Irrigant, solution

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For Veterinary Use Only

Sodium chloride 0.9% for Irrigation, 500 mL NDC 72483-207-01

Sodium chloride 0.9% for Irrigation, 1000 mL NDC 72483-207-02

NDC 72483-207-01



500 mL

SODIUM CHLORIDE 0.9% FOR IRRIGATION, USP
Not for injection • For irrigation only • Sterile, nonpyrogenic

FOR VETERINARY USE ONLY

Each 100 mL Contains: Sodium Chloride 900 mg, Water for Irrigation, USP;
Electrolyte Content (mEq/L): Sodium 154, Chloride 154
pH: 4.5-7.0; **Osmolarity:** 308 mOsm/L (calc).

No antimicrobial agent or other substance has been added.

WARNINGS: FOR IRRIGATION ONLY. NOT FOR INJECTION.

See package insert for complete warnings.

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

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.

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Made in Dominican Republic

Lot:
Exp:

NDC 72483-207-02



1000 mL

SODIUM CHLORIDE 0.9% FOR IRRIGATION, USP

Not for injection • For irrigation only • Sterile, nonpyrogenic

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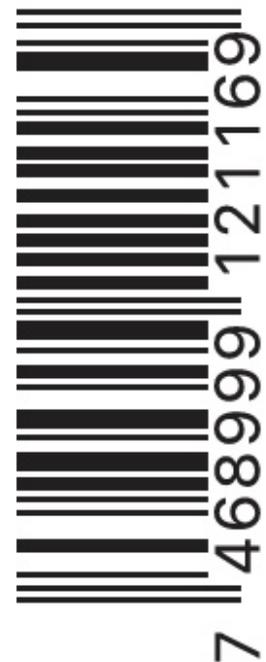
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Lot:
Exp.:

ALFA VETERINARY 0.9% SODIUM CHLORIDE

sodium chloride, solution irrigant

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:72483-207
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	900 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72483-207-02	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:72483-207-01	500 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/15/2025	

Labeler - Laboratorios Alfa SRL (815941244)

Revised: 1/2026

Laboratorios Alfa SRL