

VETERINARY 0.9% SODIUM CHLORIDE - sodium chloride injection, solution
Vedco, Inc.

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](#).

Veterinary Sodium Chloride Injection, USP

For Animal Use Only

Description

Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents or preservatives. Discard unused portion. Composition, osmolarity, and ionic concentration are shown in Table 1:

TABLE 1

Veterinary 0.9% Sodium Chloride Injection USP		
Size mL	500	1000
Sodium Chloride, USP (NaCl) (mg/100 mL)	900	900
Osmolarity (mOsmol/L) (calc)	308	308
pH	5.0 (4.5 to 7.0)	5.0 (4.5 to 7.0)
Sodium Ionic Concentration (mEq/L)	154	154
Chloride Ionic Concentration (mEq/L)	154	154

Clinical Pharmacology

Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis, depending on the clinical condition of the patient.

Indications and Usage

Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

Contraindications

None known.

Warnings

Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

The intravenous administration of Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutive states is inversely proportional to the electrolyte concentration of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.

In patients with diminished renal function, administration of Sodium Chloride Injection, USP may result in sodium retention.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

Precautions

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Caution must be exercised in the administration of Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Do not administer unless solution is clear and seal is intact.

Dosage and Administration

As directed by a veterinarian. Dosage is dependent upon the age, weight and clinical condition of the patient, as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

All injections in plastic containers are intended for intravenous administration using sterile equipment.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the veterinarian, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Over Dosage

In an event of overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings, Precautions and Adverse Events.

How Supplied

Veterinary 0.9% Sodium Chloride Injection, USP in plastic container is available as follows:

<u>NDC Code</u>	<u>Item Number</u>	<u>Size (mL)</u>	<u>Product Name</u>
50989-895-16	VINV-B925-0500	500	0.9% Sodium Chloride Injection, USP
50989-895-17	VINV-B925-1000	1000	0.9% Sodium Chloride Injection, USP

Plastic Container:

PVC Free, DEHP Free, Latex Free

Storage:

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored in the moisture overwrap at room temperature (25°C/77°F); brief exposure up to (40°C/104°F) does not adversely affect the product.

Directions for use of plastic container

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

WARNING: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.

3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in-use position and continue administration.

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

Manufactured for





Vedco, Inc.

5503 Corporate Dr.

St. Joseph, MO 64507 USA

Printed in El Salvador

For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Vedco, Inc. customer service at 1(888) 708-3326

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Principal Display Panel

NDC 50989-895-16

**Veterinary 0.9% Sodium Chloride Injection, USP
500 ml**

120 mm

NDC 50989-895-16

BIOGALENIC **VEDCO**

Veterinary 0.9% Sodium Chloride Injection, USP



EACH 100 mL CONTAINS: 900 mg SODIUM CHLORIDE USP. pH 5.0 (4.5 TO 7.0). mEq/L: SODIUM 154, CHLORIDE 154. OSMOLARITY: 308 mOsmol/L (CALC). STERILE NONPYROGENIC. SINGLE DOSE CONTAINER. CONTAINS NO ANTIMICROBIAL AGENTS OR PRESERVATIVES. USE SOLUTION PROMPTLY FOLLOWING INITIAL ENTRY. ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST IF AVAILABLE. WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE. MIX THOROUGHLY. DISCARD UNUSED PORTION. DOSAGE:

INTRAVENOUSLY AS DIRECTED BY A VETERINARIAN. SEE PACKAGE INSERT CAUTIONS. SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY. DISCARD IF LEAKS ARE FOUND. DO NOT USE UNLESS SOLUTION IS CLEAR AND SEAL IS INTACT. STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE. AVOID EXCESSIVE HEAT.

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.

500 mL



MANUFACTURED FOR:



5503 CORPORATE DR.
ST. JOSEPH, MO 64507

CUSTOMER SERVICE No.
1-888-708-3326

MADE IN EL SALVADOR

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2
3
4

120 mm

20 mm

LOT.0000000 EXP.00/0000

VINV-B925-0500

NDC 50989-895-17

Veterinary 0.9% Sodium Chloride Injection, USP
1000 ml


Scale 100%, A4

120 mm

NDC 50989-895-17

Veterinary 0.9% Sodium Chloride Injection, USP **1**

 **4** EACH 100 mL CONTAINS: 900 mg SODIUM CHLORIDE USP. pH 5.0 (4.5 TO 7.0). mEq/L: SODIUM 154, CHLORIDE 154. OSMOLARITY: 308 mOsmol/L (CALC). STERILE NONPYROGENIC. SINGLE DOSE CONTAINER. CONTAINS NO ANTIMICROBIAL AGENTS OR PRESERVATIVES. USE SOLUTION PROMPTLY FOLLOWING INITIAL ENTRY. ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST IF AVAILABLE. WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE. MIX THOROUGHLY. DISCARD UNUSED PORTION.

3 **DOSAGE:** INTRAVENOUSLY AS DIRECTED BY A VETERINARIAN. SEE PACKAGE INSERT CAUTIONS. SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY. DISCARD IF LEAKS ARE FOUND. DO NOT USE UNLESS SOLUTION IS CLEAR AND SEAL IS INTACT. STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE. AVOID EXCESSIVE HEAT.

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CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.

1000 mL

STERILE 

195 mm

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MANUFACTURED FOR:

MADE IN EL SALVADOR

5503 CORPORATE DR.
ST. JOSEPH, MO 64507

CUSTOMER
SERVICE NO.
1-888-708-3326

26 mm

LOT.00000000 EXP.00/0000

VINV-B925-1000

VETERINARY 0.9% SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:50989-895
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:L4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	900 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50989-895-16	500 mL in 1 CONTAINER		
2	NDC:50989-895-17	1000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/12/2016	

Labeler - Vedco, Inc. (021634266)

Establishment

Name	Address	ID/FEI	Business Operations
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Laboratorios Biogalenic SA de CV		851259507	api manufacture, manufacture
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Revised: 2/2016

Vedco, Inc.