VETERINARY 0.9% SODIUM CHLORIDE- sodium chloride injection, solution Assure Infusions, 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

Description:

Veterinary 0.9% Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for parenteral administration. It contains no antimicrobial agents. Discard unused portion.

Clinical Pharmacology

Veterinary 0.9% Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diures depending on the clinical condition of the patient.

Indications and Usage

Veterinary 0.9% 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 Veterinary 0.9% 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 solutions for injection contained in plastic containers are intended for administration using sterile equipment and aseptic technique. 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. Discard unused portion.

Over Dosage

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

See Warnings, Adverse Reactions and Precautions.

How Supplied

Veterinary 0.9% Sodium Chloride Injection, USP is supplied in plastic bags as follows: The plastic container is fabricated from a multi-layer, Polyolefin/Styrene-block copolymer film. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly.

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 ($25^{\circ}\text{C}/77^{\circ}\text{F}$); brief exposure up to ($40^{\circ}\text{C}/104^{\circ}\text{F}$) does not adversely affect the product.

Directions for use of plastic container

To Open

Tear overwrap down side at slit and remove solution bag. 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, turn bag so ports are upright, and no liquid remains in ports and mix thoroughly.

To add medication during solution administration

- 1. Close clamp on the administration set to stop the flow to the patient.
- 2. Prepare medication port.
- 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 while container is in the upright position.
- 6. Mix solution and medication thoroughly.
- 7. Return container to in-use position and continue administration.

Veterinary 0.9 % Sodium Chloride Injection, USP

250 mL SKU: VNS0250 ¹

Each 100 mL contains Sodium Chloride USP 900mg, Water for injection USP q.s. May contain HCl or NaOH for pH adjustment. pH:5.0 (4.5-7.0); Calc. Osmolarity 310 mOsmol/liter. Electrolytes (mEq/liter): Na+ 154mEq/L; Cl- 154mEq/L.

Indications: As a source of water and electrolytes in all species.

Dosage & Administration: As directed by a veterinarian. Dosage is dependent upon the age, weight, and clinical condition of the patient.

Warnings: Some additives may be incompatible, consult with a pharmacist when introducing additives; use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room Temperature 25°C /77°F. Store unit in moisture-barrier overwrap. Avoid excessive heat. Protect from freezing. Use only if solution is clear and container and seals are intact.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Contains no preservatives.

For Animal Use Only. Not made with natural rubber latex, DEHP, or PVC.

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NDC 83155-200-25

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Veterinary 0.9% Sodium Chloride Injection, USP

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1000 mL SKU: VNS1000	1-
Each 100 mL contains Sodium Chloride USP 900mg, Water for injection USP q.s. May contain HCl or NaOH for pH adjustment. pH:5.0 (4.5-7.0); Calc. Osmolarity 310 mOsmol/liter. Electrolytes (mEq/liter): Na+ 154mEq/L; CI- 154mEq/L.	
Dosage & Administration: As directed by a veterinarian. Dosage is dependent upon the age, weight, and clinical condition of the patient. Indications: as a source of water and electrolytes in all species. Contains no preservatives. Use solution promptly following initial entry. Discard unused portion.	3-
Warnings: Some additives may be incompatible, consult with a pharmacist when introducing additives; use aseptic techniques. Mix thoroughly. Do not store.	4-
Recommended Storage: Room Temperature 25°C /77°F. Store unit in moisture-barrier overwrap. Avoid excessive heat. Protect from freezing. Use only if solution is clear and container and seals are intact.	
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.	6-
For Animal Use Only. Not made with natural rubber latex, DEHP, or PVC.	7-
NDC 83155-200-10 NDC 83155-200-10 00383155200106	8-
MADE IN USA Wet ASSURE	9-

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Veterinary 0.9% Sodium Chloride Injection, USP

500 mL SKU: VNS0500

Each 100 mL contains Sodium Chloride USP 900mg, Water for injection USP q.s. May contain HCl or NaOH for pH adjustment. pH:5.0 (4.5-7.0); Calc. Osmolarity 310 mOsmol/liter. Electrolytes (mEq/liter): Na+ 154mEq/L; Cl-154mEq/L.

Dosage & Administration: As directed by a veterinarian. Dosage is dependent upon the age, weight, and clinical condition of the patient. Indications: as a source of water and electroyles in all species. Contains no preservatives. Use solution promptly following initial entry. Discard unused portion.

Warnings: Some additives may be incompatible, consult with a pharmacist when introducing additives; use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room Temperature 25°C /77°F. Store unit in moisture-barrier overwrap. Avoid excessive heat. Protect from freezing. Use only if solution is clear and container and seals are intact.

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

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NDC 83155-200-50

MADE IN USA





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VETERINARY 0.9% SODIUM CHLORIDE

sodium chloride injection, solution

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Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:83155-200

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingradiant Name Basis of Strangth

ingredient Name	Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, 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:83155-200-50	500 mL in 1 BAG		
2	NDC:83155-200-10	1000 mL in 1 BAG		
3	NDC:83155-200-25	250 mL in 1 BAG		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/30/2025	
OTTIEN			

Labeler - Assure Infusions, Inc (053016941)

Establishment					
Name	Address	ID/FEI	Business Operations		
Assure Infusions, Inc		053016941	manufacture, api manufacture		

Revised: 6/2025 Assure Infusions, Inc