## VETIVEX VETERINARY SODIUM CHLORIDE- sodium chloride injection, solution Dechra Veterinary Products

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.

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#### Vetivex<sup>®</sup> Veterinary 0.9% Sodium Chloride Injection, USP

For Animal Use Only

#### **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.

#### Table 1 Veterinary 0.9% Sodium Chloride Injection, USP

	Composition (mg/100mL)			Ionic Concentration (mEq/L)	
Size (mL)	Sodium Chloride, USP (NaCl)	Osmolarity (mOsmol/L) (Calculated)	рН	Sodium	Chloride
250			5.0		
500	900	308	(4.5 to 7.0)	154	154
1000			(4.5 10 7.0)	104	1.04
3000					

## Clinical Pharmacology:

Veterinary 0.9% 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:

Veterinary 0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

## Warnings:

Veterinary 0.9% 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 parenteral administration of Veterinary 0.9% 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 dilutional states is inversely proportional to the electrolyte concentrations 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 injection.

In patients with diminished renal function, administration of Veterinary 0.9% 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 judgement 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.

#### Overdosage:

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:

NDC Code	Volume		
17033-492-25	$250 \text{ mL}^*$		
17033-492-50	$500 \text{ mL}^*$		

NDC Code	Volume		
17033-492-01	$1000 \text{ mL}^*$		
17033-492-03	3000 mL <sup>†</sup>		

- \* PVC Free, DEHP Free and Latex Free Bag.
- <sup>†</sup> The plastic container is fabricated from a specially formulated polyvinyl chloride. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in animals according to USP biological tests for plastic containers, as well as tissue culture toxicity studies.

**STORAGE:** Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat.

It is recommended the product be stored in the moisture barrier 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 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 Adminis tration

- 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 administration set to stop the flow to the patient.
- 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 (U.S.A.) restricts this drug to use by or on the order of a licensed veterinarian.



DISTRIBUTED BY: Dechra Veterinary Products 7015 College Boulevard, Suite 525 Overland Park, KS 66211 Made in El Salvador. For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Dechra Veterinary Products at (866) 933-2472. © 2017 Dechra Ltd. VETIVEX<sup>®</sup> is a trademark of Dechra Ltd; all rights reserved.

Rev. 10/17

#### PRINCIPAL DISPLAY PANEL - 3000 mL Container Label

Lot.:

Expiration: NDC: 17033-492-03

Vetivex<sup>®</sup> Veterinary 0.9% Sodium Chloride Injection, USP

Sterile - Nonpyrogenic Solution

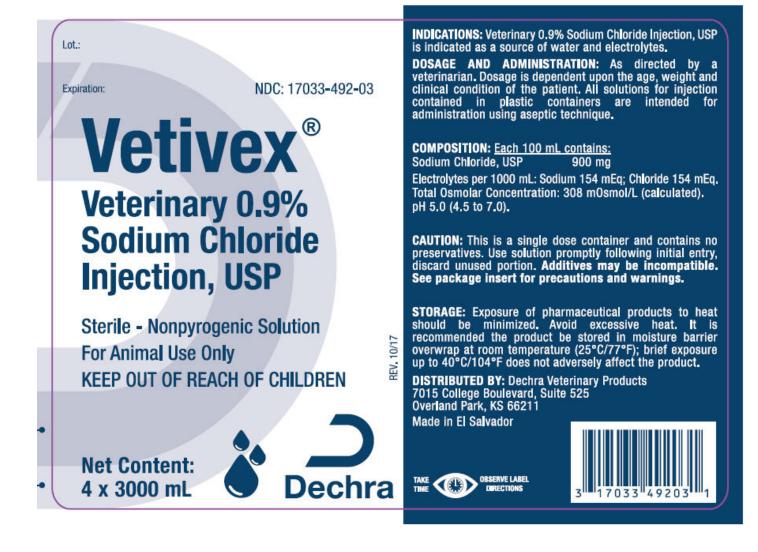
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

Net Content: 4 x 3000 mL

#### Dechra

REV. 10/17



#### VETIVEX VETERINARY SODIUM CHLORIDE

sodium chloride injection, solution

PRESCRIPTION ANIMAL DRUG					
	Item Code (Sour	rce)	e) NDC:17033-492		
INTRAVENOUS					
ety					
Ingredient Name			Basis of Strength		
(sodium cation - UNII:LYR4M0NH37, chlor	de ion -	sodium chl	loride	9 mg in 1 mL	
Ingredient Name			Strength		
	<b>ie ty</b> Ingredient Name (so dium cation - UNII:LYR4M0 NH37, chlori	<b>ie ty</b> <b>Ingredient Name</b> (so dium cation - UNII:LYR4M0NH37, chloride ion -	ie ty Ingredient Name (so dium cation - UNII:LYR4M0NH37, chloride ion - so dium chi	ie ty Ingredient Name Basis of Strength (so dium cation - UNII:LYR4M0NH37, chloride ion - so dium chloride	

Pa	ckaging					
#	Item Code	Package Description	Marketing	Start Date Ma	rketing End Date	
1 1	NDC:17033-492-25	250 mL in 1 CONTAINER				
2 N	NDC:17033-492-50	500 mL in 1 CONTAINER				
3 N	NDC:17033-492-01	1000 mL in 1 CONTAINER				
4 N	NDC:17033-492-03	3000 mL in 1 CONTAINER				
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IVI	arketing Inform	lation				
		Application Number or Monograph Citation		Marketing Start Date	Marketing End Date	
	Marketing Category	Application Number of Mono	Bruph Chanon	0		
	Marketing Category	Application Ramber of Mono	Bruph Shadon		_	

Labeler - Dechra Veterinary Products (362142734)

## Registrant - Dechra Ltd (641097493)

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