

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.

Vetivex®
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

Size (mL)	Composition (mg/100mL)		pH	Ionic Concentration (mEq/L)	
	Sodium Chloride, USP (NaCl)	Osmolarity (mOsmol/L) (Calculated)		Sodium	Chloride
250	900	308	5.0 (4.5 to 7.0)	154	154
500					
1000					
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 mL*
17033-492-50	500 mL*

NDC Code	Volume
17033-492-01	1000 mL*
17033-492-03	3000 mL†

* PVC Free, DEHP Free and Latex Free Bag.

† 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 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 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.

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Rev. 10/17

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

Vetivex[®]

Veterinary 0.9% Sodium Chloride

Injection, USP

STERILE - NONPYROGENIC SOLUTION

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

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

NDC: 17033-492-01

1000 mL

Dechra

Vetivex[®]

Veterinary 0.9% Sodium Chloride Injection, USP

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NDC: 17033-492-01

INDICATIONS:

VETERINARY 0.9% SODIUM CHLORIDE INJECTION, USP IS INDICATED AS A SOURCE OF WATER AND ELECTROLYTES.

DOSAGE AND ADMINISTRATION:

AS DIRECTED BY A VETERINARIAN. DOSAGE IS DEPENDENT UPON THE AGE, WEIGHT AND CLINICAL CONDITION OF THE PATIENT, ALL SOLUTIONS FOR INJECTION CONTAINED IN PLASTIC CONTAINERS ARE INTENDED FOR ADMINISTRATION USING ASEPTIC TECHNIQUE.

COMPOSITION:

EACH 100 mL CONTAINS: SODIUM CHLORIDE, USP 900 mg

ELECTROLYTES PER 1000 mL: SODIUM 154 mEq; CHLORIDE 154 mEq,

TOTAL OSMOLAR CONCENTRATION: 308 mOsmol/L (CALCULATED). pH 5.0 (4.5 TO 7.0).

CAUTION: THIS IS A SINGLE DOSE CONTAINER AND CONTAINS NO PRESERVATIVES. USE SOLUTION PROMPTLY FOLLOWING INITIAL ENTRY, DISCARD UNUSED PORTION. **ADDITIVES MAY BE INCOMPATIBLE. SEE PACKAGE INSERT FOR PRECAUTIONS AND WARNINGS.**

STORAGE: EXPOSURE OF PHARMACEUTICAL PRODUCTS TO HEAT SHOULD BE MINIMIZED, AVOID EXCESSIVE HEAT, IT IS RECOMMENDED THE PRODUCT BE STORED IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F); BRIEF EXPOSURE UP TO 40°C/104°F DOES NOT ADVERSELY AFFECT THE PRODUCT.

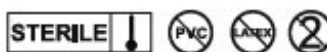


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DECHRA VETERINARY PRODUCTS
7015 COLLEGE BOULEVARD, SUITE 525,
OVERLAND PARK, KS 66211
MADE IN EL SALVADOR



OBSERVE LABEL DIRECTIONS



Rev. 01/17



1000 mL**Dechra****VETIVEX VETERINARY SODIUM CHLORIDE**

sodium chloride injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:17033-492
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sodium chloride (UNII: 451W47IQ8X) (sodium cation - UNII:LYR4M0NH37, chloride ion - UNII:Q32ZN48698)	sodium chloride	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17033-492-25	250 mL in 1 CONTAINER		
2	NDC:17033-492-50	500 mL in 1 CONTAINER		
3	NDC:17033-492-01	1000 mL in 1 CONTAINER		
4	NDC:17033-492-03	3000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/01/2016	

Labeler - Dechra Veterinary Products (362142734)**Registrant** - Dechra Ltd (641097493)