VETIVEX VETERINARY HYPERTONIC- 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 HYPERTONIC SALINE SOLUTION 7.2%, USP

For Animal Use Only

Description:

Veterinary Hypertonic Saline Solution 7.2%, 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 Hypertonic saline solution 7.2%, USP

Size (mL)	Sodium Chlorine (mg/mL)	Osmolarity (mEq/L)	рН	Sodium (mEq/L)	Chloride (mEq/L)
1000	7200	2464	(4.5 - 7.0)	1232	1232

Clinical Pharmacology:

Veterinary Hypertonic saline solutions 7.2%, USP has value as a source of water, electrolytes and calories.

Indications and Usage:

For use in replacement therapy of sodium, chloride and water which may become depleted in many diseases.

Warnings:

This product contains no preservatives. Use entire contents when first opened. Discard any unused solution.

The parenteral administration of Veterinary Hypertonic saline solution 7.2%, 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 Hypertonic saline

solution 7.2%, 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 HYPERTONIC SALINE SOLUTION 7.2%, USP to patients receiving corticosteroids or corticotropin. Do not administer unless solution is clear, and seal is intact.

Dosage and administration:

Warm to body temperature and administer slowly by intravenous or subcutaneous injection. The amount and rate of administration must be judged by the veterinarian in relation to the condition being treated and the clinical response of the animal, being careful to avoid overhydration.

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:

HYPERTONIC SALINE SOLUTION 7.2%, USP is supplied in plastic bags as follows:

NDC	Volume	
17033-502-01	1000 mL	

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 of (15°C - 30°C) OR (59°F - 86°F). Keep out of reach of children,

Directions for use of plastic container

To open:

Tear overwrap downside 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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REV07/21

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

Vetivex®

Hypertonic Saline Solution 7.2%, 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 LICENCED VETERINARIAN.

NDC: 17033-502-01

INDICATIONS:

FOR USE IN REPLACEMENT THERAPY OF SODIUM, CHLORIDE AND WATER WHICH MAY BECOME DEPLETED IN MANY DISEASES.

DOSAGE AND ADMINISTRATION:

HORSES / CATTLE: 50 TO 100 ML PER 100 LB BODY WEIGHT. WARM TO BODY TEMPERATURE AND ADMINISTER SLOWLY BY INTRAVENOUS OR SUBCUTANEOUS INJECTION. THE AMOUNT AND RATE OF ADMINISTRATION MUST BE JUDGED BY THE VETERINARIAN IN RELATION TO THE CONDITION BEING TREATED AND THE CLINICAL RESPONSE OF THE ANIMAL, BEING CAREFUL TO AVOID OVERHYDRATION.

COMPOSITION:

EACH 100 mL OF STERILE AQUEOUS SOLUTION CONTAINS 7.2 g OF SODIUM CHLORIDE.

MILLIEQUIVALENTS PER LITER:

CATIONS 1,232 mEq - ANIONS 1,232 mEq/L TOTAL OSMOLARITY IS 2,464 MILLIOSMOLES PER LITER. PH 4.5 - 7.0

WARNING: THIS PRODUCT CONTAINS NO PRESERVATIVES. USE ENTIRE CONTENTS WHEN FIRST OPENED. DISCARD ANY UNUSED SOLUTION.

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.

DISTRIBUTED BY: DECHRA VETERINARY PRODUCTS 7015 COLLEGE BOULEVARD, SUITE 525, OVERLAND PARK, KS 66211

MADE IN EL SALVADOR STERILE

TAKE
TIME
OBSERVE LABEL
DIRECTIONS

Rev. 05/21

1000 mL Dechra

LOT.0000000 EXP.00/0000

Vetivex®

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VETIVEX VETERINARY HYPERTONIC

sodium chloride injection, solution

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Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:17033-502

Route of Administration INTRAVENOUS, SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	7.20 mg in 100 mL

Inactive Ingredients			
	Ingredient Name	Strength	
WATER (UNII: 0590F0KO0R)			

Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:17033-502-01	1000 mL in 1 CONTAINER			

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	12/01/2021			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

Labeler - Dechra Veterinary Products (362142734)

Registrant - Dechra Ltd (641097493)

Revised: 11/2021 Dechra Veterinary Products