VETIVEX HARTMANNS- sodium chloride, sodium lactate, potassium chloride, and calcium 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®
Hartmann's Solution for Injection

For Animal Use Only

Description:

Hartmann's Solution for Injection is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for parenteral administration. It contains no antimicrobial agents. Discard unused portions.

Table 1 Hartmann's Solution for Injection

Size (mL)	Composition (mg/100mL)				Osmolarity (mOsmol/L) (Calculated)	pH	Ionic Concentration (mEq/L)				
	Sodium Chloride, USP (NaCl)	Sodium Lactate, USP ($C_3H_5NaO_3$)	Potassium Chloride, USP (KCl)	Calcium Chloride Dihydrate, USP ($CaCl_2 \cdot 2H_2O$)			Sodium	Potassium	Calcium	Chloride	Lactate
3000	600	317	40	27	278	6.5 (5.0 to 7.0)	131	5	4	111	29
5000											

Clinical Pharmacology:

Hartmann's Solution for Injection has value as a source of water and electrolytes. lt is capable of inducing diuresis depending on the clinical condition of the patient.

Hartmann's Solution for Injection produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage:

Hartmann's Solution for Injection is indicated as a source of water and electrolytes or as an alkalinizing agent.

Warnings:

Do not administer to horses by intraperitoneal injection.

Hartmann's Solution for Injection 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.

Hartmann's Solution for Injection should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Hartmann's Solution for Injection should be used with great care in patients with metabolic or respiratory alkalosis. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

Hartmann's Solution for Injection should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The parenteral administration of Hartmann's Solution for Injection 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 Hartmann's Solution for Injection may result in sodium or potassium retention.

Hartmann's Solution for Injection is not for use in the treatment of lactic acidosis.

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.

Hartmann's Solution for Injection must be used with caution. Excess administration may result in metabolic alkalosis.

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

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.

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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.

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:

Hartmann's Solution for Injection is supplied in plastic bags as follows:

NDC Code	Volume
17033-482-03	3000mL*
17033-482-05	5000mL*

* 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.

Rev. 10/17

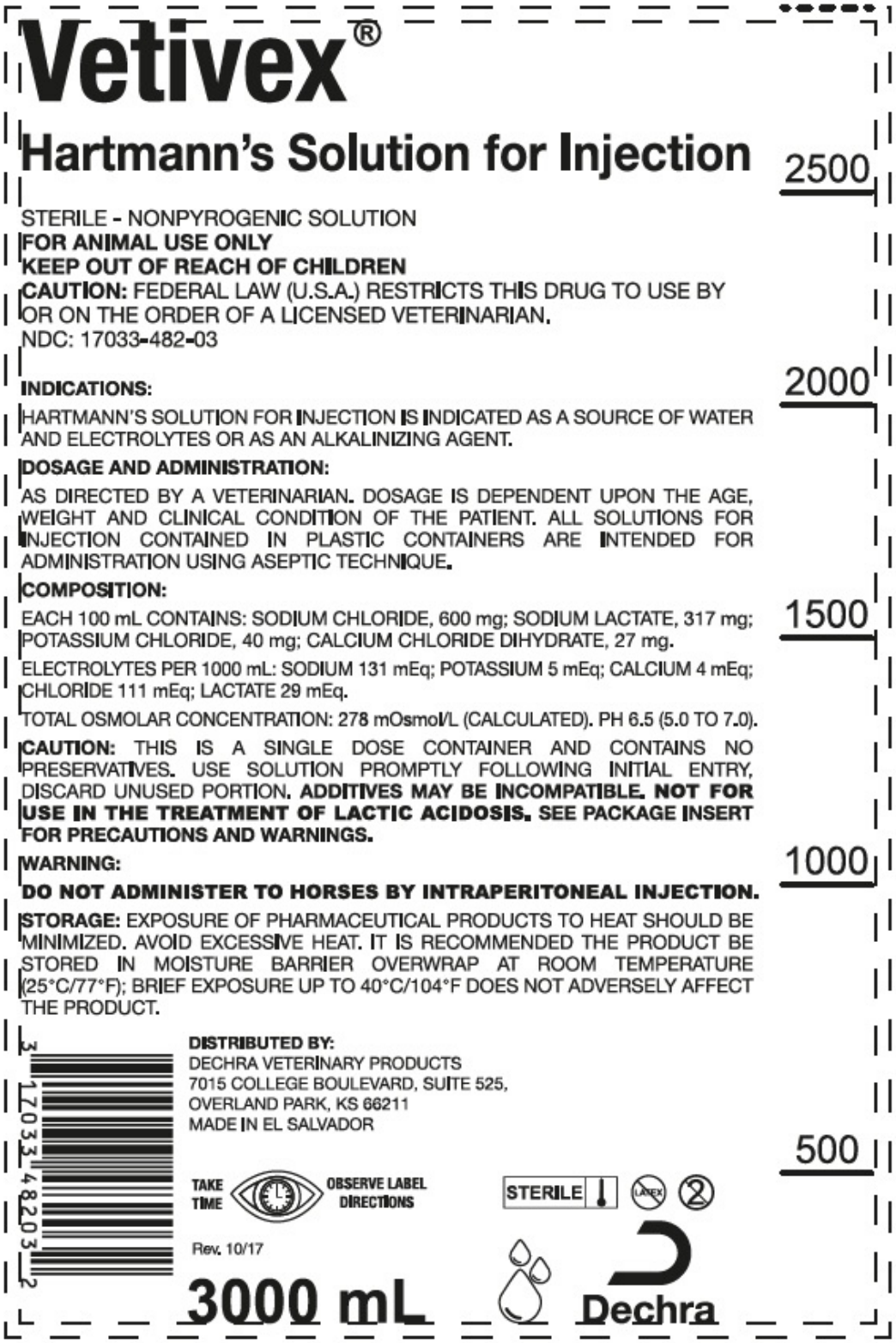
PRINCIPAL DISPLAY PANEL - 3000 mL Container Label

Vetivex®

Hartmann's Solution for Injection

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: 17033-482-03

3000 mL
Dechra



VETIVEX HARTMANNS

sodium chloride, sodium lactate, potassium chloride, and calcium chloride injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:17033-482
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium chloride (UNII: 451W47IQ8X) (Chloride ion - UNII:Q32ZN48698, Sodium cation - UNII:LYR4M0NH37)	Sodium chloride	600 mg in 100 mL
Sodium Lactate (UNII: TU7HW0W0QT) (Lactic acid, unspecified form - UNII:33X04XA5AT, sodium cation - UNII:LYR4M0NH37)	Sodium Lactate	317 mg in 100 mL
Potassium Chloride (UNII: 660YQ98I10) (Potassium cation - UNII:295O53K152, chloride ion - UNII:Q32ZN48698)	Potassium Chloride	40 mg in 100 mL
Calcium Chloride (UNII: M4I0D6VV5M) (Calcium cation - UNII:2M83C4R6ZB, chloride ion - UNII:Q32ZN48698)	Calcium Chloride	27 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Sodium (UNII: 9NEZ333N27)	
Potassium (UNII: RWP5GA015D)	
Calcium (UNII: SY7Q814VUP)	
Chloride ion (UNII: Q32ZN48698)	
Lactic acid, unspecified form (UNII: 33X04XA5AT)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17033-482-03	3000 mL in 1 CONTAINER		
2	NDC:17033-482-05	5000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/01/2017	

Labeler - Dechra Veterinary Products (362142734)

Registrant - Dechra Ltd (641097493)

Revised: 9/2020 Dechra Veterinary Products