VETIVEX VETERINARY PHYLYTE- sodium chloride, sodium gluconate, sodium acetate, potassium chloride, and magnesium 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 pHyLyte® Injection pH 7.4
(Multiple Electrolytes Injection, Type 1, USP)

For Animal Use Only

Description:

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is a sterile, nonpyrogenic isotonic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents or preservatives. Discard unused portion. The pH is adjusted with sodium hydroxide.

Table 1: Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)

Size (mL)	Composition (mg/100mL)						pH	Ionic Concentration (mEq/L)						kcal/L
	Sodium Chloride, USP (NaCl)	Sodium Gluconate, USP ($C_6H_{11}NaO_7$)	Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$)	Potassium Chloride, USP (KCl)	Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$)	Osmolarity (mOsmol/L) (calc)		Sodium	Potassium	Magnesium	Chloride	Acetate	Gluconate	Caloric Content
1000 3000 5000	526	502	368	37	30	294	7.4 (6.5 to 8.0)	140	5	3	98	27	23	21

Clinical Pharmacology:

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) administered intravenously has value as a source of water and electrolytes. It is capable of inducing diuresis, depending on the clinical condition of the patient.

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage:

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is indicated as a source of water and electrolytes or as an alkalinizing agent.

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i.e. as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes. Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components.

Contraindications:

None known.

Warnings:

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, 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.

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) 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.

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate 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.

The intravenous administration of Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, 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 injection. 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 pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) may result in sodium or potassium 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.

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, 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 injections in plastic containers are intended for intravenous administration using sterile equipment.

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, Precautions and Adverse Events.

How Supplied:

Veterinary pHyLyte® Injection pH 7.4 (Multiple Electrolytes Injection, Type 1, USP) in plastic container is available as follows:

NDC Code	Volume
17033-501-01	1000 mL*
17033-501-03	3000 mL†
17033-501-05	5000 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 (25ºC/77ºF); brief exposure up to 40ºC/104ºF does not adversely affect the product.

Directions for use of plastic container

To Open

Tear overwrap down side at slit and remove solution container. 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 (USA) 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

TAKE TIME  **OBSERVE LABEL DIRECTIONS**

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

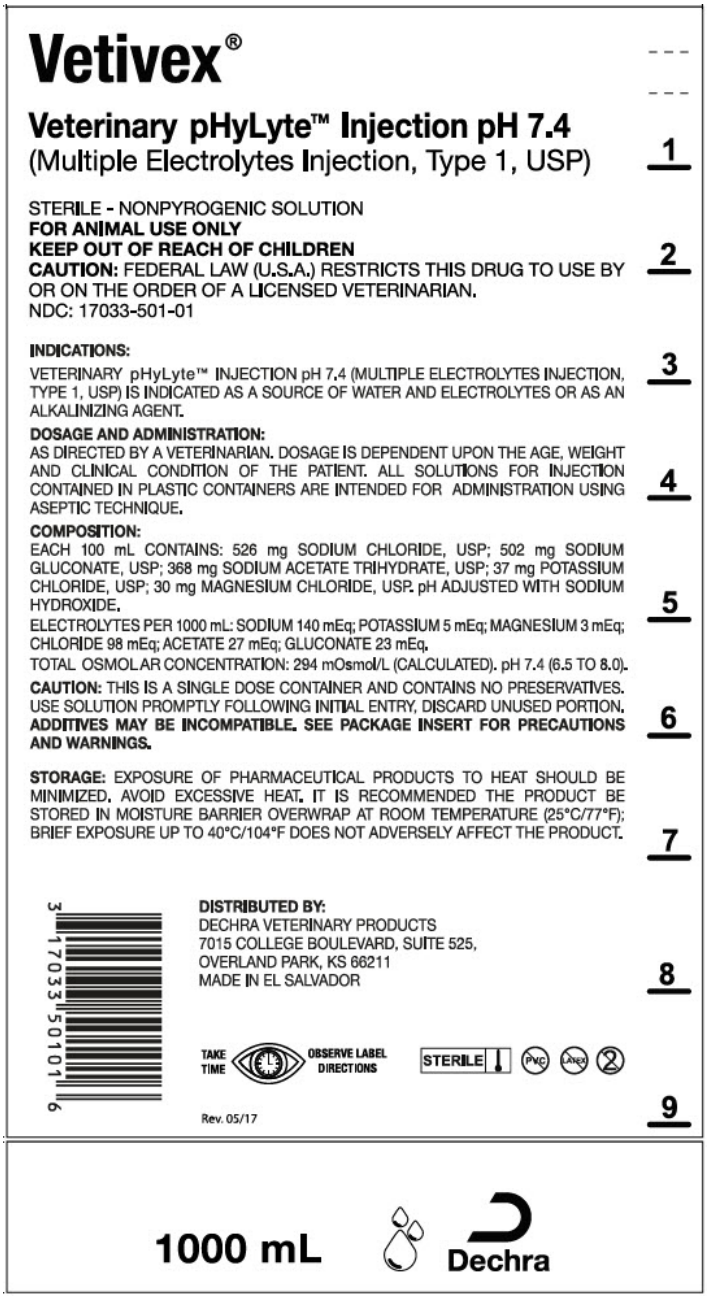
PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

Vetivex®

Veterinary pHyLyte™ Injection pH 7.4
(Multiple Elecrolytes Injection, Type 1, 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: 17033-501-01

1000 mL
Dechra



VETIVEX VETERINARY PHYLYTE

sodium chloride, sodium gluconate, sodium acetate, potassium chloride, and magnesium chloride injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:17033-501
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	526 mg in 100 mL
Sodium Gluconate (UNII: R6Q3791S76) (GLUCONIC ACID - UNII:R4R8J0Q44B, sodium cation - UNII:LYR4M0NH37)	Sodium Gluconate	502 mg in 100 mL
Sodium Acetate (UNII: 4550K0SC9B) (ACETATE ION - UNII:569DQM74SC, SODIUM CATION - UNII:LYR4M0NH37)	Sodium Acetate	368 mg in 100 mL
Potassium Chloride (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, chloride ion - UNII:Q32ZN48698)	Potassium Chloride	37 mg in 100 mL
Magnesium Chloride (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, chloride ion - UNII:Q32ZN48698)	Magnesium Chloride	30 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:17033-501-01	1000 mL in 1 CONTAINER		
2	NDC:17033-501-05	5000 mL in 1 CONTAINER		
3	NDC:17033-501-03	3000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/01/2017	

Labeler - Dechra Veterinary Products (362142734)

Registrant - Dechra Ltd (641097493)

Revised: 9/2020

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