VETIVEX VETERINARY LACTATED RINGERS AND DEXTROSE- dextrose monohydrate, sodium lactate, sodium chloride, 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®
Veterinary Lactated Ringer's and 5% Dextrose Injection, USP

For Animal Use Only

Description:

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Discard unused portion.

Table 1 Veterinary Lactated Ringer's and 5% Dextrose Injection, USP

Size (mL)	Composition (mg/100mL)					Osmolarity (mOsmol/L) (Calculated)	pH	Ionic Concentration (mEq/L)					kcal/L
	Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$)	Sodium Chloride, USP (NaCl)	Sodium Lactate, USP ($C_3H_5NaO_3$)	Potassium Chloride, USP (KCl)	Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$)			Sodium	Potassium	Calcium	Chloride	Lactate	Caloric Content
1000	5000	600	310	30	20	525	5.0 (4.0 to 6.5)	130	4	2.7	109	28	180

Clinical Pharmacology:

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP has value as a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP 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:

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP is indicated as a source of water, electrolytes and calories or as an alkalinizing agent.

Contraindications:

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings:

Do not administer to horses by intraperitoneal injection.

Veterinary Lactated Ringer's and 5% Dextrose 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.

Veterinary Lactated Ringer's and 5% Dextrose Injection, 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 Lactated Ringer's and 5% Dextrose Injection, USP 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.

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Veterinary Lactated Ringer's and 5% Dextrose 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 Lactated Ringer's and 5% Dextrose Injection, USP may result in sodium or potassium retention.

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP 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.

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP must be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of Lactated Ringer's and 5% Dextrose Injection, USP to patients receiving corticosteroids or corticotropin.

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP is hyperosmolar. Administration of substantially hyperosmolar solutions may cause irritation of the vein, including phlebitis. Hyperosmolar solutions should only be given to animals who are hydrated and receiving maintenance fluid therapy. It is inappropriate to use as a replacement fluid in dehydrated animals where rapid fluid shifts are still occurring from the vascular space into extravascular spaces.

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 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:

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP is supplied in plastic bags as follows:

NDC Code	Volume
17033-494-01	1000 mL*

* PVC Free, DEHP Free and Latex Free Bag.

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. 01/17

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

Vetivex®

Veterinary Lactated Ringer's and
5% Dextrose 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: 17033-494-01

1000 mL
Dechra

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NDC: 17033-494-01

INDICATIONS:

VETERINARY LACTATED RINGER'S AND 5% DEXTROSE INJECTION, USP IS INDICATED AS A SOURCE OF WATER, ELECTROLYTES AND CALORIES OR AS AN ALKALINIZING AGENT.

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: DEXTROSE HYDROUS, USP 5000 mg; SODIUM CHLORIDE, USP 600 mg; SODIUM LACTATE, USP 310 mg; POTASSIUM CHLORIDE, USP 30 mg; CALCIUM CHLORIDE, USP 20 mg.

ELECTROLYTES PER 1000 mL: SODIUM 130 mEq; POTASSIUM 4 mEq; CALCIUM 2.7 mEq; CHLORIDE 109 mEq; LACTATE 28 mEq.

TOTAL OSMOLAR CONCENTRATION: 525 mOsmol/L (CALCULATED). pH 5.0 (4.0 TO 6.5).

CAUTION: THIS IS A SINGLE DOSE CONTAINER AND CONTAINS NO PRESERVATIVES. USE SOLUTION PROMPTLY FOLLOWING INITIAL ENTRY, DISCARD UNUSED PORTION. SOLUTION IS HYPEROSMOLAR AND SHOULD ONLY BE USED FOR MAINTENANCE FLUID THERAPY IN HYDRATED PATIENTS. **ADDITIVES MAY BE INCOMPATIBLE. NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS.** SEE PACKAGE INSERT FOR PRECAUTIONS AND WARNINGS.

WARNING:
DO NOT ADMINISTER TO HORSES BY INTRAPERITONEAL INJECTION.

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

TAKE TIME OBSERVE LABEL DIRECTIONS STERILE PVC LATEX

Rev. 01/17

1 2 3 4 5 6 7 8 9

1000 mL

Dechra

VETIVEX VETERINARY LACTATED RINGERS AND DEXTROSE

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

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:17033-494
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
dextrose monohydrate (UNII: LX22YL083G) (anhydrous dextrose - UNII:5SL0G7R0OK)	dextrose monohydrate	50 mg in 1 mL
sodium lactate (UNII: TU7HW0W0QT) (lactic acid, unspecified form - UNII:33X04XA5AT, sodium cation - UNII:LYR4M0NH37)	sodium lactate	3.1 mg in 1 mL
sodium chloride (UNII: 451W47IQ8X) (sodium cation - UNII:LYR4M0NH37, chloride ion - UNII:Q32ZN48698)	sodium chloride	6 mg in 1 mL
potassium chloride (UNII: 660YQ98I10) (potassium cation - UNII:295O53K152, chloride ion - UNII:Q32ZN48698)	potassium chloride	0.3 mg in 1 mL
calcium chloride (UNII: M4I0D6VV5M) (calcium cation - UNII:2M83C4R6ZB, chloride ion - UNII:Q32ZN48698)	calcium chloride	0.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17033-494-01	1000 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)

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