VETERINARY LACTATED AND 5% DEXTROSE - dextrose hydrous, sodium chloride, sodium lactate, potassium chloride, calcium chloride injection, solution
Ivali LLC

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.

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 or preservatives. Discard unused portion. Composition, osmolarity, and ionic concentration are shown in Table 1

TABLE 1

Veterinary Lactated Ringer's and 5% Dextrose Injection, USP	
Size mL	1000
Dextrose Hydrous, USP ($C_6H_{12}O_6 \bullet H_2O$) (g/100mL)	5
Sodium Chloride, USP (NaCl) (mg/100mL)	600
Sodium Lactate, USP ($C_3H_5NaO_3$) (mg/100mL)	310
Potassium Chloride, USP (KCl) (mg/100mL)	30
Calcium Chloride, USP ($CaCl_2 \bullet 2H_2O$) (mg/100mL)	20
Osmolarity (mOsmol/L) (calc)	525
pH	5.0 (4.0 to 6.5)
Sodium Ionic Concentration (mEq/L)	130
Potassium Ionic Concentration (mEq/L)	4
Calcium Ionic Concentration (mEq/L)	2.7
Chloride Ionic Concentration (mEq/L)	109
Lactate Ionic Concentration (mEq/L)	28
Caloric Content (kcal/L)	180

Clinical Pharmacology

Lactated Ringer's and 5% Dextrose Injection, USP has value as a source of water, electrolytes and calories. Normal physiologic range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. It is capable of inducing diuresis, depending on the clinical condition of the patient.

Lactated Ringer's and 5% Dextrose Injection, USP produces a metabolic alkalinilizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires consumption of hydrogen cations

Indications and Usage

Lactated Ringer's and 5% Dextrose Injection, USP is indicated as a source of water and 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

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.

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.

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.

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 Lactated Ringer's and 5% Dextrose Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, over hydration, congested states, or pulmonary edema. The risk of dilutive states is inversely proportional to the electrolyte concentration 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 injections.

In patients with diminished renal function, administration of Lactated Ringer's and 5% Dextrose Injection, USP may result in sodium or potassium retention.

Lactated Ringer's and 5% Dextrose Injection, USP is not used for 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.

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 corticotrophin.

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

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 injections in plastic containers are intended for intravenous 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.

Hyperosmolar glucose-containing solutions are meant to be maintainence solutions used in animals in which fluids are not shifting rapidly from the vaascualr compartment to a third body fluid space. They are usually not used as volume replacement solutions.

Over Dosage

In an event of over hydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings. Precautions and Adverse Events.

How Supplied

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

NDC Code	Size (mL)	Product Name
86094-897-01	1000	Lactated Ringer's and 5% Dextrose Injection, USP

Plastic Container:

PVC Free, DEHP Free, Latex Free. The volumetric scales on the single dose plastic container should only be used as a reference. For precise dosage of volumes it is recommeded the use of IV Infusion pump or IV Burrette.

Storage:

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored in the moisture overwrap at room temperature (25°C/77°F); brief exposure up to (40°C/104°F) does not adversely affect the product.

Storage

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored in the moisture overwrap at room temperature (250C/770F); brief exposure up to (400C/1040F) 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 Administration1. 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 administration1. 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 administration1. Close clamp on the set.

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 restricts this drug to use by or on the order of a licensed veterinarian.

Manufactured for:

IVALI LLC
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Aventura Florida

Printed in Argentina
For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call IVALI LLC. Customer service at 1-305-692-7665

Principal Display Panel

NDC 86094-897-01

IVALI

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

1000 mL

VETERINARY LACTATED AND 5% DEXTROSE

dextrose hydrous, sodium chloride, sodium lactate, potassium chloride, calcium chloride injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86094-897
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	600 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM LACTATE	310 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	30 mg in 100 mL
CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698)	CALCIUM CHLORIDE	20 mg in 100 mL

DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86094-897-01	1000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/11/2018	

Labeler - Ivali LLC (081136076)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS JAYOR S.R.L.		979312485	api manufacture, manufacture

Revised: 5/2018 Ivali LLC