VETERINARY LACTATED - 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 Injection, USP

For Animal Use Only

Description

Lactated Ringer's Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents or preservatives. Discard unused portion. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1:

TABLE 1

Veterinary Lactated Ringer's Injection, USP					
Size mL	250	500	1000	3000	5000
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)	273				
pH	6.5 (6.0 to 7.5)				
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)	9				

Clinical Pharmacology

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

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

Indications and Usage

Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes or as an alkalinizing agent

Contraindications

None known.

Warnings

Do not administer to horses by intraperitoneal injection.

Lactated Ringer's 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 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 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 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 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 Injection, USP may result in sodium or potassium retention.

Lactated Ringer's 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 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 Injection, USP to patients receiving corticosteroids or corticotrophin.

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.

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 Injection, USP in plastic container is available as follows:

HOW SUPPLIED

NDC Code	Volume
86094-898-25	250 mL*
86094-898-50	500 mL*
86094-898-01	1000 mL*
86094-898-03	3000 mL**
86094-898-05	5000 mL**

*PVC Free, DEHP Free and Latex Free Bag. 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.

**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 withing 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 accourding 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 that the product be stored in the moisture overwrap at room temperature (25^0C/77^0F); brief exposure up to (40^0C/104^0F) 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 (USA) restricts this drug to use by or on the order of a licensed veterinarian.

Manufactured for:

IVALI LLC18205 Biscayne Blvd., Suite 2202
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 86094-898-25
Veterinary Lactated Ringer's Injection, USP
250 ml

NDC 86094-898-25

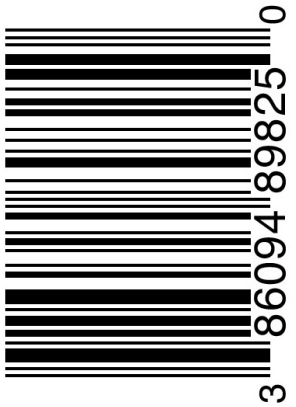
IVALI™

Veterinary Lactated Ringer's Injection, USP

50

Each 100 mL contains: 600 mg Sodium Chloride USP, 310 mg Sodium Lactate USP, 30 mg Potassium Chloride USP, 20 mg Calcium Chloride USP. pH 6.5 (6.0 to 7.5). mEq/L: Sodium 130, Potassium 4, Calcium 2.7, Chloride 109, Lactate 28. Osmolarity: 273 mOsmol/L (calc). Sterile Nonpyrogenic Single Dose Container. Contains no antimicrobial agents or preservatives. Use solution promptly following initial entry. Not for use in the Treatment of Lactic Acidosis. Additives may be incompatible. Consult with pharmacist if available. When introducing additives use aseptic technique. Mix thoroughly. Discard unused portion. Dosage: Intravenously as directed by a veterinarian. See package insert cautions. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Do not administer simultaneously with blood. Do not use unless solution is clear and seal is intact. Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use. Avoid excessive heat.

100



For Animal Use Only
Keep out of Reach of Children
Caution: Federal Law (USA) restricts this drug to use by or on the order of a licensed veterinarian.

150

250 mL

Manufactured for:

IVALI™

STERILE

PVC LATEX 2

200

Rev.04/18

Made in Argentina

18205 Biscayne Blvd., Suite 2202
Aventura, FL 33160

NDC 86094-898-50
Veterinary Lactated Ringer's Injection, USP

500 ml

86094-898-01
Veterinary Lactated Ringer's Injection, USP
1000 ml

86094-898-03
Veterinary Lactated Ringer's Injection, USP
3000 ml

NDC 50989-898-05

Veterinary Lactated Ringer's Injection, USP
5000 ml

IVALI™

Veterinary Lactated Ringer's Injection, USP

4000

Each 100 mL contains: 600 mg Sodium Chloride USP, 310 mg Sodium Lactate USP, 30 mg Potassium Chloride USP, 20 mg Calcium Chloride USP. pH 6.5 (6.0 to 7.5). mEq/L: Sodium 130, Potassium 4, Calcium 2.7, Chloride 109, Lactate 28. Osmolarity: 273 mOsmol/L (calc). Sterile Nonpyrogenic Single Dose Container. Contains no antimicrobial agents or preservatives. Use solution promptly following initial entry. Not for use in the Treatment of Lactic Acidosis. Additives may be incompatible. Consult with pharmacist if available. When introducing additives use aseptic technique. Mix thoroughly. Discard unused portion. Dosage: Intravenously as directed by a veterinarian. See package insert cautions. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Do not administer simultaneously with blood. Do not use unless solution is clear and seal is intact. Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use. Avoid excessive heat.

3500

3000

2500

2000

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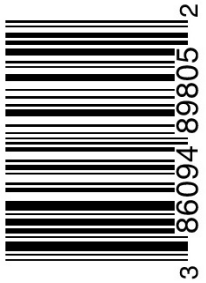
1500

5000 mL

1000



Rev. 04/18

500

Manufactured for:

IVALI™

Made in Argentina

18205 Biscayne Blvd., Suite 2202
Aventura, FL 33160

VETERINARY LACTATED

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

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:86094-898
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

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:86094-898-25	250 mL in 1 CONTAINER		
2	NDC:86094-898-50	500 mL in 1 CONTAINER		
3	NDC:86094-898-01	1000 mL in 1 CONTAINER		
4	NDC:86094-898-03	3000 mL in 1 PACKAGE		
5	NDC:86094-898-05	5000 mL in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/26/2018	

Labeler - Ivali LLC (081136076)

Establishment

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

Revised: 4/2018 Ivali LLC