ALFA VETERINARY LACTATED RINGERS- lactated ringers sodium chloride,sodium lactate, potassium chloride,calcium chloride injection, solution
Laboratorios Alfa SRL

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.

DESCRIPTION

Veterinary Lactated Ringers Injection, USP is a sterile, non-pyrogenic solution for fluid replenishment

in single dose containers for intravenous administration. Discard unused portion. It contains no antimicrobial agents.

Table 1.Veterinary Lactated Ringers Injection, USP

Size mL	Composition (g/100 mL)				Osmolarity		Ionic Concentration (mEq/L)					Caloric
	Sodium Chloride USP	Sodium Lactate	Potassium Chloride USP	Calcium Chloride USP	(mOsmol/L) Calculated	pH	Sodium	Potasium	Calcium	Chloride	Lactate	Content (Kcal/L)
100 250 500 1000	0.6	0.31	0.03	0.02	274	6-7.5	130.50	4.0	2.70	109.80	27.69	9

No venting is necessary during infusion.

CLINICAL PHARMACOLOGY

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Veterinary Lactated Ringer’s Injection, USP is contraindicated in patients with a known hypersensitivity to sodium lactate.

WARNINGS

Veterinary 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.

Veterinary 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.

Veterinary 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.

Veterinary Lactated Ringer’s Injection, USP should not be administered simultaneously with blood

through the same administration set because of the likelihood of coagulation.

The container label for these injections bears the statement: **Do not administer simultaneously with blood.**

The intravenous administration of Veterinary 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 Veterinary Lactated Ringer's Injection, USP may result in sodium retention proportional to the electrolyte concentrations of the injections.

Veterinary Lactated Ringer's Injection, USP is not for use in the treatment of lactic acidosis

Keep out of the reach of children.

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

Do not administer unless solution is clear and both seal and container are 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 discolorations 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 over hydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings, Precautions and Adverse Reactions.

STORAGE

Store below 30°C (86°F).

PRECAUTION OF USE OF THE BOTTLE

This is a single dose container and does not contain preservatives.

Use the solution immediately after the bottle is opened, discard the remaining one.
Squeeze and inspect the bottle, discard if leaks are found or if the solution contains visible and solid particles.

Do not administer simultaneously with blood.
Do not use it unless solution is clear and seal is intact, the solution containing dextrose may be contraindicated in patients with a known allergy to corn or corn products.

DIRECTIONS FOR USE PLASTIC CONTAINER:

Preparation and administration
1. Check for minute leaks by squeezing the container firmly. If leaks are found, discard solution as sterility may be impaired.
2. Suspend container from eyelet support.
3. Remove Plastic protector from ports area at the bottom of container.
4. Hold the bottle in vertical position and inset pyrogen free IV administration set in the outlet port. Use aseptic Technique

To Add Medication
WARNING: Additives may be incompatible.
To add medication before solution administration
1. Prepare medication site.
2. Using syringe with 18 to 21 gauge needle, puncture inlet 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 set.
2. Prepare medication site.
3. Using syringe with 18 to 21 gauge needle, puncture inlet port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Mix solution and medication thoroughly.
6. 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.

Package Insert

For animal use only.

ALFA VETERINARY LACTATED RINGER'S INJECTION, USP
Laboratorios ALFA

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA.

Veterinary Lactated Ringer's Injection, USP
For Animal Use Only
Sterile – Non-pyrogenic solution

DESCRIPTION:

Veterinary Lactated Ringer's Injection, USP is a sterile, non-pyrogenic solution for fluid replenishment in single dose containers for intravenous administration. Discard unused portion. It contains no antimicrobial agents.

COMPOSICION:

Table 1.Veterinary Lactated Ringer's Injection, USP

Size (mL)	Composition (g/100 mL)				Osmolarity (mOsmol/L) Calculated	pH	Ionic Concentration (mEq/L)					Caloric Content (Kcal/L)
	Sodium Chloride USP	Sodium Lactate	Potassium Chloride USP	Calcium Chloride USP			Sodium	Potasium	Calcium	Chloride	Lactate	
100	0.6	0.31	0.03	0.02	274	6-7.5	130.50	4.0	2.70	109.80	27.69	9
250												
500												
1000												

No venting is necessary during infusion.

CLINICAL PHARMACOLOGY:

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

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

INDICATIONS AND USAGE:

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

CONTRAINDICATIONS:

Veterinary Lactated Ringer's Injection, USP is contraindicated in patients with a known hypersensitivity to sodium lactate.

WARNINGS:

Veterinary 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.

Veterinary 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.

Veterinary 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.

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

The container label for these injections bears the statement: **Do not administer simultaneously with blood.**

The intravenous administration of Veterinary 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 Veterinary Lactated Ringer's Injection, USP may result in sodium retention proportional to the electrolyte concentrations of the injections.

Veterinary Lactated Ringer's Injection, USP is not for use in the treatment of lactic acidosis.

Keep out of the reach of children.

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

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.

Do not administer unless solution is clear and both seal and container are 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 discolorations 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 over hydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings , Precautions and Adverse Reactions.

PACKAGING:
VET RINGERS LACTATED 1000 ML...**NDC: 72483-202-10**
VET RINGERS LACTATED 500 ML.....**NDC: 72483-202-05**
VET RINGERS LACTATED 250 ML.....**NDC: 72483-202-25**
VET RINGERS LACTATED 100 ML.....**NDC: 72483-202-01**

STORAGE:
Store below 30ºC (86ºF).

ROUTE OF ADMINISTRATION:
Intravenous

PRECAUTION OF USE OF THE BOTTLE:
This is a single dose container and does not contain preservatives.

Use the solution immediately after the bottle is opened, discard the remaining one. Squeeze and inspect the bottle, discard if leaks are found or if the solution contains visible and solid particles.

Do not administer simultaneously with blood.
Do not use it unless solution is clear and seal is intact, the solution containing dextrose may be contraindicated in patients with a known allergy to corn or corn products.

DIRECTIONS FOR USE PLASTIC CONTAINER:
Preparation and administration

1. Check for minute leaks by squeezing the container firmly. If leaks are found, discard solution as sterility may be impaired.
2. Suspend container from eyelet support.
3. Remove Plastic protector from ports area at the bottom of container.
4. Hold the bottle in vertical position and inset pyrogen free IV administration set in the outlet port. Use aseptic Technique

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WARNING: Additives may be incompatible.
To add medication before solution administration
1. Prepare medication site.
2. Using syringe with 18 to 21 gauge needle, puncture inlet 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 set.
2. Prepare medication site.
3. Using syringe with 18 to 21 gauge needle, puncture inlet port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Mix solution and medication thoroughly.
6. 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 by:
LABORATORIOS ALFA S.R.L.,
Santo Domingo, Dominican Republic
Revised March 2019

PRINCIPAL DISPLAY PANEL

LACTATED RINGER'S INJECTION , USP

Veterinary Use

Sterile and NonProgenic Solution

Keep out of reach of Children.

For Animal Use Only.

Take Time - Observe label directions

Manufactured by:

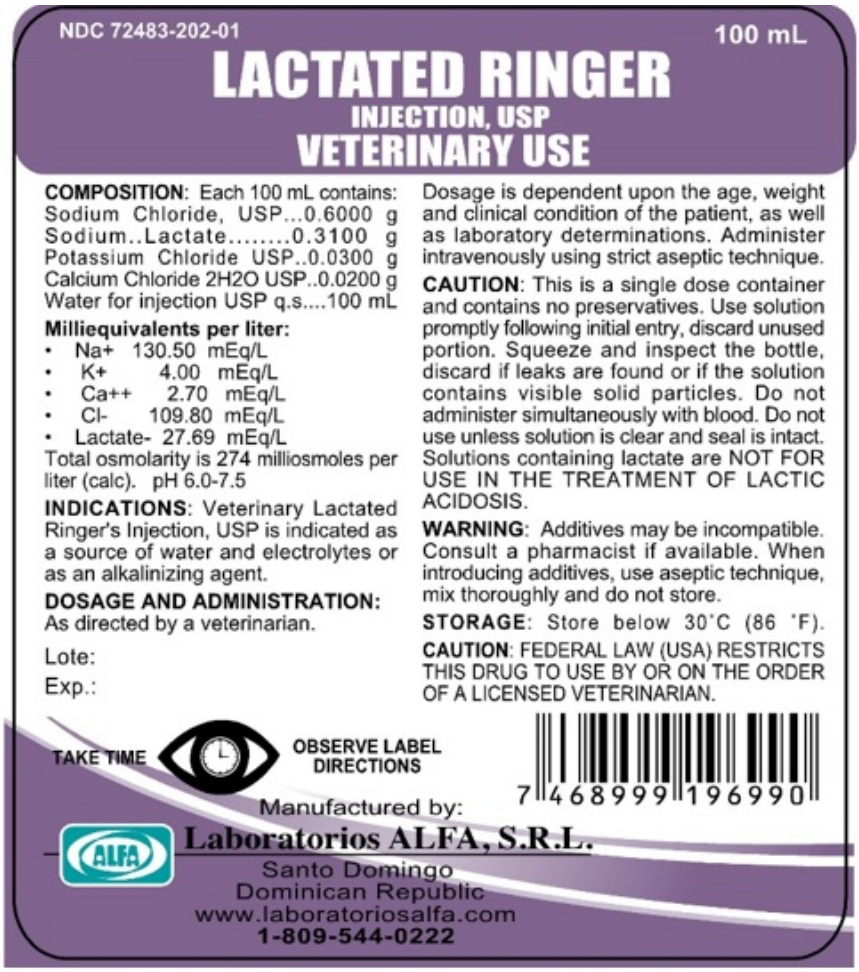
Laboratorios Alfa, SRL

Santo Domingo

Domincan Republic

www.laboratoriosalfa.com

+1-809-544-0222



NDC 72483-202-25 250 mL

LACTATED RINGER
INJECTION, USP
VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION
KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL USE ONLY

COMPOSITION:
Each 100 mL contains:
Sodium Chloride, USP...0.6000 g
Sodium..Lactate.....0.3100 g
Potassium Chloride USP..0.0300 g
Calcium Chloride 2H2O USP....0.0200 g
Water for injection USP q.s.....100 mL

Milliequivalents per liter:
- Na+ 130.50 mEq/L
- K+ 4.00 mEq/L
- Ca++ 2.70 mEq/L
- Cl- 109.80 mEq/L
- Lactate- 27.69 mEq/L

Total osmolarity is 274 milliosmoles per liter (calc). pH 6.0-7.5

INDICATIONS:
Veterinary Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes 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, as well as laboratory determinations. Administer intravenously using strict aseptic technique.

Lot.:

Exp.:

CAUTION:
This is a single dose container and contains no preservatives. Use solution promptly following initial entry, discard unused portion. Squeeze and inspect the bottle, discard if leaks are found or if the solution contains visible solid particles. Do not administer simultaneously with blood. Do not use unless solution is clear and seal is intact. Solutions containing lactate are NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS.

WARNING:
Additives may be incompatible. Consult a pharmacist if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

STORAGE:
Store below 30°C (86 °F).

CAUTION:
FEDERAL LAW (USA) RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.

TAKE TIME OBSERVE LABEL DIRECTIONS

7 468999 196983

Manufactured by:
Laboratorios ALFA, S.R.L.
Santo Domingo
Dominican Republic
www.laboratoriosalfa.com
1-809-544-0222

NDC 72483-202-05 500 mL

LACTATED RINGER
INJECTION, USP
VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION **FOR ANIMAL USE ONLY**
KEEP OUT OF REACH OF CHILDREN

COMPOSITION: Each 100 mL contains:
Sodium Chloride, USP.....0.6000 g
Sodium..Lactate.....0.3100 g
Potassium Chloride USP.....0.0300 g
Calcium Chloride 2H2O USP....0.0200 g
Water for injection USP q.s.....100 mL

Milliequivalents per liter:
- Na+ 130.50 mEq/L
- K+ 4.00 mEq/L
- Ca++ 2.70 mEq/L
- Cl- 109.80 mEq/L
- Lactate- 27.69 mEq/L

Total osmolarity is 274 milliosmoles per liter (cacl). pH 6.0-7.5

INDICATIONS: Veterinary Lactated Ringer's Injection, USP is indicated as a source of water and electrolytes 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, as well as laboratory determinations. Administer intravenously using strict aseptic technique.

CAUTION:
This is a single dose container and contains no preservatives. Use solution promptly following initial entry, discard unused portion. Squeeze and inspect the bottle, discard if leaks are found or if the solution contains visible solid particles. Do not administer simultaneously with blood. Do not use unless solution is clear and seal is intact.
Solutions containing lactate are NOT FOR USE IN THE TREATMENT OF LACTIC ACIDOSIS.

WARNING:
Additives may be incompatible. Consult a pharmacist if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

STORAGE:
Store below 30°C (86 °F).

CAUTION:
FEDERAL LAW (USA) RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.

Lot.:

Exp.:

TAKE TIME  OBSERVE LABEL DIRECTIONS

7 468999 196976

Manufactured by:
Laboratorios ALFA, S.R.L.
Santo Domingo
Dominican Republic
www.laboratoriosalfa.com
1-809-544-0222

ALFA VETERINARY LACTATED RINGERS

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

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:72483-202
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	600 mg in 100 mL
SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	310 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	30 mg in 100 mL

CALCIUM CHLORIDE (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CHLORIDE	20 mg in 100 mL	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72483-202-10	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:72483-202-05	500 mL in 1 BOTTLE, PLASTIC		
3	NDC:72483-202-24	250 mL in 1 BOTTLE, PLASTIC		
4	NDC:72483-202-01	100 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/29/2019	

Labeler - Laboratorios Alfa SRL (815941244)

Revised: 2/2020 Laboratorios Alfa SRL