VETERINARY LACTATED RINGERS- sodium lactate, sodium chloride, potassium chloride, and calcium chloride injection, solution
Assure Infusion Inc

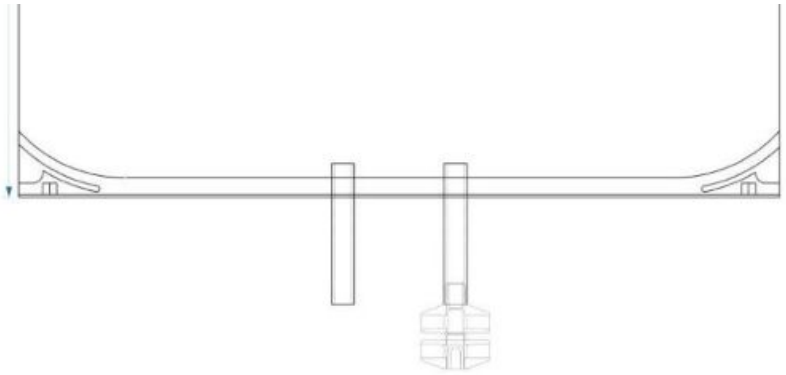
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Veterinary Lactated Ringers

Dosage and Administration Section

As directed by a licensed veterinarian. Dosage is dependent upon the age, weight and clinical condition of the patient. Use the entire content once opened. Discard unused portion.

Lactated Ringers



Los accesorios que se encuentran en la imagen adjunta son solo una visualización de como quedaría el diseño estampado en la bolsa.

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VETERINARY LACTATED RINGER'S INJECTION, USP [redacted]

[redacted] For Veterinary Use Only

STERILE, NONPYROGENIC

Disclaimer:

This product is intended for veterinary use only. It is manufactured in accordance with current good manufacturing practices (cGMP) and is distributed under the supervision of a licensed veterinarian. While not reviewed by the FDA, it is formulated to meet recognized standards for sterility, safety, and efficacy in veterinary injection procedures.

Route of Administration:
• Intravenous. Not for human use

Description:
Lactated Ringer's Injection, USP is a sterile, nonpyrogenic, parenteral solution intended for fluid and electrolyte replenishment. It is supplied in single-dose containers for intravenous administration. The solution contains no preservatives, antimicrobial agents, bacteriostatic agents, or added buffers. The solution is formulated with Sterile Water for Injection, USP as the vehicle. May contain: HCl or NaOH for pH adjustment. Details on composition, osmolarity, pH, and caloric content are provided in Table 1.

Table 1
Veterinary Lactated Ringer's Injection, USP

Size (mL)	Composition (mg/100mL)				Osmolarity (mOsmol/L) (Calculated)	pH	Ionic Concentration (mEq/L)					kcal/L
	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
5000	600	310	30	20	273	6.5 (6.0 to 7.5)	130	4	2.7	109	28	9

Clinical Pharmacology:
Lactated Ringer's for Injection, USP serves as a source of water and electrolytes and may promote diuresis depending on the animal's clinical condition. The solution also exerts a metabolic alkalinizing effect. Lactate ions are metabolized primarily to carbon dioxide and water, a process that consumes hydrogen cations and helps correct acid-base imbalances.

Indications and Usage:
Lactated Ringer's for Injection, USP solution is indicated for a parenteral source of water and as an alkalinizing agent in the treatment of conditions associated with fluid and electrolyte loss.

Warnings:

- Not for the treatment of lactic acidosis
- Use with great care in animals with congestive heart failure, severe renal insufficiency, sodium retaining conditions, hyperkalemia or potassium-retaining

conditions

- Use with caution in animals with metabolic or respiratory alkalosis
- Administer lactate ions cautiously in animals with impaired lactate metabolism (e.g., severe hepatic insufficiency)
- Do not administer simultaneously with blood through the same administration set due to the risk of coagulation
- Intravenous administration may cause fluid or solute overload, especially in animals with impaired renal function
- **Keep out of the reach of children.**

Precautions:

- Single-use container. No venting required for flexible bags
- Use aseptic technique when administering or adding additives
- Monitor fluid balance, electrolytes, and acid-base status during therapy
- Use cautiously in pregnant or lactating animals; safety has not been established
- Supplement essential electrolytes, minerals, and vitamins as needed

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- Administer sodium-containing solutions cautiously in animals receiving corticosteroids, corticotropin, or with salt-retaining conditions
- Inspect solution for clarity, particulate matter, and container for integrity before and during use
- Do not connect containers in series; discontinue pumping before the container is empty to prevent air embolism
- Replace IV administration sets at least every 24 hours
- Do not administer unless the solution is clear and the container and seal are intact

Use in Pregnant or Lactating Animals:
The safety of Lactated Ringer's for Injection, USP has not been established in pregnant or lactating animals. Use only when the potential benefits justify the potential risks to the fetus or neonate. Veterinary discretion is advised.

Adverse Reactions:
SOLUTION-RELATED REACTIONS
These may occur due to the composition of the solution:

- Electrolyte disturbances such as:
  - Hypernatremia (e.g., in animals with sodium retention)
  - Hyperkalemia (e.g., in animals with renal impairment or urinary obstruction)
- Fluid overload, especially in animals with compromised renal or cardiovascular function
- Metabolic alkalosis, particularly in animals with impaired lactate metabolism

Technique-Related Reactions:
These may result from improper administration practices:

- Febrile response
- Infection at the injection site
- Local pain or irritation
- Venous thrombosis or phlebitis at the injection site
- Extravasation (leakage of fluid into surrounding tissue)
- Air embolism, if containers are connected in series or not properly primed
- If an adverse reaction occurs, discontinue administration immediately, evaluate the animal, and institute appropriate therapeutic measures and save the remainder of the fluid for examination if deemed necessary.

Adverse Event Reporting:
To report suspected adverse reactions, contact VetAssure at 1-863-292-2211 or report to the FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

Dosage and Administration:

- Read Precautions and Warnings section.
- Administer only as directed by a licensed veterinarian. Dosage depends on the animal's age, weight, clinical condition, and laboratory findings.
- Inspect parenteral products visually for particulate matter and discoloration before administration whenever solution and container permit.
- Use sterile equipment for intravenous administration.
- Warm the solution to body temperature and infuse slowly.
- Additives may be incompatible. Complete compatibility information is not available; do not use additives known to be incompatible. If additives are introduced, use aseptic technique and mix thoroughly.
- Do not store solutions containing additives. Discard any 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:
Lactated Ringer's, USP for Injection is available in the following flexible bag (IV) size:

NDC Code	Volume	SKU
83155-202-05	5000 mL	VRL5000

83155-202-05	5000 mL	VRL5000

The flexible bag is made from polyvinyl chloride (PVC) which is a flexible and resistant material that provides an excellent compatibility with a maximum number of pharmaceuticals, reducing the risk of interactions. Not made with natural rubber latex, DEHP. No venting is necessary during infusion.

Instruction for Use:
LOT NUMBER AND EXPIRY DATE:
Before use, verify the lot number and expiration date printed on the container label. Do not use if the product is expired or if the lot number is missing or illegible.

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.

863.292.2211 Vet@AssureIV.com

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For Flexible Bag (IV):
To Open
Remove the overwrap downside at the slit and remove the solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard the container as solution path sterility may be impaired. 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 the inner bag firmly. If leaks are found, discard the solution, as sterility may be compromised. If supplemental medication is desired, follow the "To Add Medication" directions below.

Preparation for Administration
1. This is a single-use container and does not contain preservatives.
2. Suspend the container from the eyelet support.
3. Remove the protector from the outlet port area at the bottom of the container.
4. No venting is necessary during infusion.
5. Hold the bag in a vertical position and insert pyrogen-free IV administration set in the outlet port. Use an aseptic technique.

Introduction of Additives
WARNING: Additives may be incompatible. When introducing additives, continue using aseptic technique.

To Add Medication (Before or During Administration)
1. Prepare medication site.
2. Using a syringe with an 18-to-21-gauge needle, puncture the inlet port and inject.
3. For administration before infusion, mix thoroughly and inspect. For high-density medication such as potassium chloride, squeeze the port while the container is upright and mix thoroughly.
4. For administration during infusion, close the clamp, reposition the container, evacuate ports, mix thoroughly, and resume infusion.

Storage:
Store in moisture barrier overwrap at room temperature 25°C (77°F). Avoid excessive heat. Protect from freezing.

SHELF LIFE: 48 months from the date of manufacture when stored as directed. Once the container is opened, use immediately. Discard any unused portion; do not store for later use.

REGULATORY COMPLIANCE: This product is manufactured in an FDA-registered facility and is listed in accordance with applicable FDA drug listing requirements for veterinary products. For more information, consult the distributor, manufacturer or visit the FDA Drug Registration and Listing System (DRLS).

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

TAKE TIME | OBSERVE LABEL DIRECTIONS

Vet ASSURE™
275 Century Blvd. Bartow, FL 33830

MANUFACTURED BY:
Laboratorios ALFA S.R.L.

DISTRIBUTED BY:
Assure Infusions
Made in Dominican Republic
For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call 863-292-2211

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

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:83155-202
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM LACTATE (UNII: TU7HW0W0QT) (LACTIC ACID - UNII:33X04XA5AT, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM LACTATE	310 mg in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	600 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	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:83155-202-05	2 in 1 CASE		
1		5000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/02/2026	

Labeler - Assure Infusion Inc (053016941)

Registrant - Assure Infusion Inc (053016941)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Alfa SRL		817468920	manufacture, api manufacture