LACTATED RINGER AND DEXTROSE- sodium chloride, sodium lactate, potassium chloride, calcium chloride and dextrose monohydrate injection, solution
ASPEN VETERINARY

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.

Lactated Ringer and Dextrose

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

Description

Lactated Ringer and 5% Dextrose Injection is a sterile, non-pyrogenic solution intended for fluid and electrolyte replenishment and caloric supply in single dose containers. May be administered intravenously using aseptic technique. It contains no antimicrobial agents. Discard any unused portion. Composition, osmolarity, pH and ionic concentration and caloric content are shown in Table 1.

Table 1

Composition (g/L)	Dextrose Hydrous	Sodium Chloride	Potassium Chloride	Calcium Chloride	Sodium Lactate*
	50.0	6.0	0.30	0.20	3.10
Ionic Concentration (mEq/L)	**Sodium**	**Potassium**	**Calcium**	**Chloride**	**Lactate**
	130	4	2.7	109	28

*Sodium Lactate USP – (S)-enantiomer
Osmolarity (mOsmol/L) (calc): 525mOsmol per liter
Caloric Content (kcal/L): 180
pH: 5.0 (limit 4.0 – 6.5)

The container is free of PVC and phthalates. The container meets the requirements of USP and is registered with FDA.

Clinical Pharmacology

Lactated Ringer and 5% Dextrose Injection is intended to restore the electrolyte balance, caloric content and water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient. Lactated Ringer and 5% Dextrose Injection produces a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications

Lactated Ringer and 5% Dextrose Injection is indicated as a source of water, electrolytes and calories for all species. It is also used as an alkalinizing agent.

Contraindications

Lactated Ringer and 5% Dextrose Injection is contraindicated in patients with a known hypersensitivity to sodium lactate; congestive heart failure or severe impairment of renal function; clinical states in which the administration of sodium and chloride is detrimental.

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

Warnings

The introduction of additives to any solution, regardless of type of container, requires special attention to ensure that no incompatibilities result. While some incompatibilities are readily absorbed, one must be aware that subtle physical, chemical and pharmacological incompatibilities can occur. The medical literature, the package insert and other available sources of information should be reviewed for thorough understanding of possible incompatibilities.

Lactated Ringer and 5% Dextrose Injection 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 and sodium retention; patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present; 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 and 5% Dextrose Injection should not be administered simultaneously with blood through the same administration set because of likelihood of coagulation.

The intravenous administration of Lactated Ringer and 5% Dextrose Injection can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, over-hydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overloading 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 and 5% Dextrose Injection may result in sodium or potassium retention.

Do not administer to animals with inadequate renal function. Not for use in 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 and evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Precautions

This is a single dose unit. It contains no preservatives. Use entire contents when first opened.

Do not administer unless solution is clear and both seal and container are intact.

Solution must be warmed to body temperature prior to administration and administered at a slow rate. Use solution promptly following initial entry.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged therapy or whenever the condition of the patient warrants such evaluation.

Lactated Ringer and 5% Dextrose Injection should be used with caution. Excess administration may result in metabolic alkalosis.

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

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

Dosage and Administration

To be used as directed by a licensed veterinarian. The dosage of the Lactated Ringer and 5% Dextrose Injection is dependent upon the age, weight and clinical conditions of the patient as well as laboratory determinations. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

For use in one patient on one occasion only. Discard any unused portion. Care should be taken with administration technique to avoid administration site reactions and infection.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Over-dosage

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

Storage

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (86°F/30°C). Protect from freezing.

Directions for use of plastic container

To Open

Tear overwrap 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 solution container 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 plastic protector from inlet/outlet port at bottom of container.
3. Attach administration set.

To Add Medication

WARNING: Additives may be incompatible.
To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 0.63mm to 0.80mm needle, puncture 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 the clamp on the administration set.
2. Prepare medication site.
3. Using syringe with 0.63mm to 0.80mm needle, puncture 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:
Aspen Veterinary Resources® Ltd.
Liberty, MO 64068, USA
www.aspenveterinaryresources.com

Manufactured by:
Sypharma Pty Ltd
27 Healey Road, Dandenong
Victoria 3175 Australia

For customer service email:
info@aspenveterinaryresources.com

Rev. 04/16

Lactated Ringer and 5% Dextrose Injection 1000mL

aspen VETERINARY RESOURCES, LTD.

Lactated Ringer and 5% Dextrose Injection

Approx. 100

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

900

1000mL (33.81 fl oz)

200

Each 100mL contains:

DEXTROSE HYDROUS	5g
SODIUM CHLORIDE	600mg
POTASSIUM CHLORIDE	30mg
CALCIUM CHLORIDE DIHYDRATE	20mg
SODIUM LACTATE	310mg

800

mEq/L SODIUM 130, POTASSIUM 4, CALCIUM 2.7, CHLORIDE 109, LACTATE 28

pH: 5.0 (4.0 to 6.5), HYPERTONIC, OSMOLARITY: 525mOsmol/L (calc)

INDICATIONS: AS A SOURCE OF WATER, ELECTROLYTES AND CALORIES OR AS AN ALKALINIZING AGENT IN ALL SPECIES.

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. SEE PACKAGE INSERT.

CAUTION: SOLUTION MUST BE WARMED TO BODY TEMPERATURE PRIOR TO ADMINISTRATION AND ADMINISTERED AT A SLOW RATE. THIS IS A SINGLE DOSE UNIT. IT CONTAINS NO PRESERVATIVES. USE SOLUTION PROMPTLY FOLLOWING INITIAL ENTRY. USE ENTIRE CONTENTS WHEN FIRST OPENED. SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY. 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.

WARNING: DO NOT ADMINISTER TO ANIMALS WITH INADEQUATE RENAL FUNCTION. NOT FOR USE IN LACTIC ACIDOSIS. ADDITIVES MAY BE INCOMPATIBLE, CONSULT WITH VETERINARIAN IF AVAILABLE. WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE. MIX THOROUGHLY. IF ENTIRE CONTENTS ARE NOT USED, DISCARD THE UNUSED PORTION.

STORAGE: STORE BELOW 86ºF/30ºC (ROOM TEMPERATURE) IN BARRIER OVER-POUCH UNTIL READY FOR USE. PROTECT FROM FREEZING.

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

MANUFACTURED FOR: ASPEN VETERINARY RESOURCES® LTD., LIBERTY, MO 64068, USA
WWW.ASPENVETERINARYRESOURCES.COM

MANUFACTURED BY: SYPHARMA PTY LTD, 27 HEALEY ROAD, DANDENONG VICTORIA 3175 AUSTRALIA.

FOR CUSTOMER SERVICE EMAIL: INFO@ASPENVETERINARYRESOURCES.COM

NDC NUMBER: 46066-514-06

BARCODE:

A529SPH

REV. 04/16

LOT:

EXP:

LACTATED RINGER AND DEXTROSE

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

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:46066-514

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5 g 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, 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
SODIUM LACTATE (UNII: TU7HW0W0QT) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:33X04XA5AT)	SODIUM LACTATE	310 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:46066-514-06	12 in 1 CASE		
1		1000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/27/2016	

Labeler - ASPEN VETERINARY (627265361)

Registrant - SYPHARMA PTY LTD (753786292)

Establishment

Name	Address	ID/FEI	Business Operations
SYPHARMA PTY LTD		753786292	manufacture, pack, sterilize