VETONE- lactated ringers sodium chloride,sodium lactate,potassium chloride,calcium chloride injection, solution
MWI

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.

VETone Lactated Ringer's Injection

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

DESCRIPTION

VetOne Lactated Ringer's Injection is a sterile, non-pyrogenic solution intended for fluid and electrolyte

replenishment in single dose containers. May be administered intravenously, subcutaneously or

intraperitoneally (except in horses) using aseptic technique. It contains no antimicrobial agents.

Discard any unused portion. Composition, osmolarity, pH and ionic concentration are shown In Table 1

Table 1

Composition (g/L)	Sodium Chloride	Potassium Chloride	Calcium Chloride	Sodium Lactate*	
	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): 273mOsmol per liter

pH: 6.5 (limit 6.0 - 7.5)

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

CLINICAL PHARMACOLOGY

A multiple electrolyte intravenous solution is intended to restore the electrolyte balance and water for hydration. A combination of multiple electrolytes and sodium lactate, an alkalinizing agent, will provide electrolyte balance and normalize the pH of the acid-base of the physiological system.

INDICATIONS

VetOne Lactated Ringer′s Injection is indicated as a source of water and electrolytes for all species. It is also used as an alkalinizing agent.

CONTRAINDICATIONS

VetOne Lactated Ringer′s 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.

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.

VetOne Lactated Ringer′s 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.

VetOne Lactated Ringer′s Injection 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.

VetOne Lactated Ringer′s Injection should be used with great care in patients Wth 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.

VetOne Lactated Ringer′s Injection should not be administered simultaneously with blood through the same

administration set because of likelihood of coagulation.

The intravenous administration of VetOne Lactated Ringer′s 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 VetOne Lactated Ringer′s Injection may result in

sodium or potassium retention.

Do not administer to horses by intraperitoneal injection. Do not administer to animals with inadequate renal function. Not for use in lactic acidosis.

ADVERSE REACTIONS

Adverse reactions may occur due to the solution or the technique of administration including fever response, infection at the site of injection or allergic reactions. Prolonged intravenous infusion of this type of product may cause 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.

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.

VetOne Lactated Ringer′s Injection should be used with caution. Excess administration may result in metabolic

alkalosis.

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.

Reactions which may occur because of the solution or the technique of administration, include febrile response, infection at the site of injection, extravasation, and hypervolemia.

If an adverse reaction occur, discontinue the infusion and evaluate the patient, institute appropriate therapeutic

countermeasures, and save remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION

To be used as directed by a licensed veterinarian. The dosage of the VetOne Lactated Ringer′s 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. Consult with Pharmacist, if available. If, in the informed judgement of the doctor,

it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced.

Do not store solutions containing additives.

OVERDOSAGE

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

PACKS SUPPLIED

VetOne Lactated Ringer′s Injection in plastic container is available as follows:

Size (mL)	Item Code	NDC
250	501209	13985-933-25
500	501200	13985-933-50
1000	501201	13985-933-01
5000	501203	13985-933-05

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 owerwrap 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.

Made in Australia
Manufactured by:
Sypharma Pty Ltd
27 Healey Road, Dandenong
Victoria 3175 Australia
Distributed by: MWI
Boise,ID 83705
www.VetOne.net
Iss.04/18

VetoneLactatedRingersInjection250ml

Lactated Ringer's
Injection
FOR ANIMAL USE ONLY
250 mL (8.45 fl. oz.)

ACTIVE INGREDIENTS: EACH 100 mL CONTAINS SODIUM CHLORIDE 600 mg; SODIUM LACTATE 310 mg; POTASSIUM CHLORIDE 30 mg; CALCIUM CHLORIDE, DIHYDRATE 20 mg, IN WATER FOR INJECTION.

mEq/LITER: SODIUM 130; CHLORIDE 109; LACTATE 28; POTASSIUM 4; CALCIUM 2.7.

OSMOLARITY: 273 mOsmo/LITER (CALC).

pH: 6.5 (6.0 – 7.5)

INDICATIONS: 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, SUBCUTANEOUSLY OR INTRAPERITONEALLY (EXCEPT IN HORSES) USING STRICT ASEPTIC TECHNIQUE. SEE PACKAGE INSERT.

CAUTION: SOLUTION SHOULD BE WARMED TO BODY TEMPERATURE PRIOR TO ADMINISTRATION AND ADMINISTERED AT A SLOW RATE. STERILE NONPYROGENIC SOLUTION. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. THIS IS A SINGLE DOSE UNIT. IT CONTAINS NO PRESERVATIVES. USE PROMPTLY UPON INITIAL ENTRY. IF ENTIRE CONTENTS ARE NOT USED, DISCARD UNUSED PORTION. DO NOT USE SIMULTANEOUSLY WITH BLOOD.

WARNING: DO NOT ADMINISTER TO HORSES BY INTRAPERITONEAL INJECTION. DO NOT ADMINISTER TO ANIMALS WITH INADEQUATE RENAL FUNCTION. 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. IF ENTIRE CONTENTS ARE NOT USED, DISCARD THE UNUSED PORTION.

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

KEEP OUT OF REACH OF CHILDREN.

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

LATEX

Manufactured For:
MWI, Boise, ID 83705 www.VetOne.net

Manufactured By:
Sypharma Pty Ltd, 27 Healey Road, Dandenong VIC 3175 Australia

LOT:

EXP:

NDC 13985-933-25

VET one®

V1 501209

3 13985 93325 7

Iss. 05/18

VetoneLactatedRingersInjection500ml

Lactated Ringer's

Injection

FOR ANIMAL USE ONLY

500 mL (16.91 fl. oz.)

ACTIVE INGREDIENTS: EACH 100 mL CONTAINS SODIUM CHLORIDE 600 mg; SODIUM LACTATE 310 mg; POTASSIUM CHLORIDE 30 mg; CALCIUM CHLORIDE, DIHYDRATE 20 mg, IN WATER FOR INJECTION.

mEq/LITER: SODIUM 130; CHLORIDE 109; LACTATE 28; POTASSIUM 4; CALCIUM 2.7.

OSMOLARITY: 273 mOsmo/LITER (CALC).

pH: 6.5 (6.0 – 7.5)

INDICATIONS: 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, SUBCUTANEOUSLY OR INTRAPERITONEALLY (EXCEPT IN HORSES) USING STRICT ASEPTIC TECHNIQUE. SEE PACKAGE INSERT.

CAUTION: SOLUTION SHOULD BE WARMED TO BODY TEMPERATURE PRIOR TO ADMINISTRATION AND ADMINISTERED AT A SLOW RATE. STERILE NONPYROGENIC SOLUTION. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. THIS IS A SINGLE DOSE UNIT. IT CONTAINS NO PRESERVATIVES. USE PROMPTLY UPON INITIAL ENTRY. IF ENTIRE CONTENTS ARE NOT USED, DISCARD UNUSED PORTION. DO NOT USE SIMULTANEOUSLY WITH BLOOD.

WARNING: DO NOT ADMINISTER TO HORSES BY INTRAPERITONEAL INJECTION. DO NOT ADMINISTER TO ANIMALS WITH INADEQUATE RENAL FUNCTION. 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. IF ENTIRE CONTENTS ARE NOT USED, DISCARD THE UNUSED PORTION.

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

KEEP OUT OF REACH OF CHILDREN.

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

LATEX

Lot:

Exp:

Manufactured For:
MWI, Boise, ID 83705 www.VetOne.net

Manufactured By:
Sypharma Pty Ltd, 27 Healey Road, Dandenong VIC 3175 Australia

NDC 13985-933-50

VET one®

V1 501200

3 13985 93350 9

Iss. 05/18

VetoneLactatedRingersInjection1000ml

Lactated Ringer's

Injection

FOR ANIMAL USE ONLY

1000 mL (33.81 fl. oz.)

ACTIVE INGREDIENTS: EACH 100 mL CONTAINS SODIUM CHLORIDE 600 mg; SODIUM LACTATE 310 mg; POTASSIUM CHLORIDE 30 mg; CALCIUM CHLORIDE, DIHYDRATE 20 mg, IN WATER FOR INJECTION.

mEq/LITER: SODIUM 130; CHLORIDE 109; LACTATE 28; POTASSIUM 4; CALCIUM 2.7.

OSMOLARITY: 273 mOsmo/LITER (CALC).

pH: 6.5 (6.0 – 7.5)

INDICATIONS: 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, SUBCUTANEOUSLY OR INTRAPERITONEALLY (EXCEPT IN HORSES) USING STRICT ASEPTIC TECHNIQUE. SEE PACKAGE INSERT.

CAUTION: SOLUTION SHOULD BE WARMED TO BODY TEMPERATURE PRIOR TO ADMINISTRATION AND ADMINISTERED AT A SLOW RATE. STERILE NONPYROGENIC SOLUTION. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. THIS IS A SINGLE DOSE UNIT. IT CONTAINS NO PRESERVATIVES. USE PROMPTLY UPON INITIAL ENTRY. IF ENTIRE CONTENTS ARE NOT USED, DISCARD UNUSED PORTION. DO NOT USE SIMULTANEOUSLY WITH BLOOD.

WARNING: DO NOT ADMINISTER TO HORSES BY INTRAPERITONEAL INJECTION. DO NOT ADMINISTER TO ANIMALS WITH INADEQUATE RENAL FUNCTION. 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. IF ENTIRE CONTENTS ARE NOT USED, DISCARD THE UNUSED PORTION.

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

KEEP OUT OF REACH OF CHILDREN.

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

LOT:

EXP:

Manufactured For:
MWI, Boise, ID 83705 www.VetOne.net

Manufactured By:
Sypharma Pty Ltd, 27 Healey Road, Dandenong VIC 3175 Australia

NDC 13985-933-01

VETone®

V1 501201

3 13985 93301 1

Iss. 05/18

VetoneLactatedRingersInjection5000ml

VETONE

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

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:13985-933
Route of Administration	INTRAVENOUS, SUBCUTANEOUS, INTRAPERITONEAL		

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) (SODIUM CATION - UNII:LYR4M0NH37, LACTIC ACID - UNII:33X04XA5AT)	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:13985-933-25	24 in 1 CARTON		
1		250 mL in 1 BAG		
2	NDC:13985-933-50	24 in 1 CARTON		
2		500 mL in 1 BAG		
3	NDC:13985-933-01	12 in 1 CARTON		
3		1000 mL in 1 BAG		
4	NDC:13985-933-05	2 in 1 CARTON		
4		5000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/03/2018	

Labeler - MWI (019926120)

Registrant - Sypharma Pty Ltd (753786292)

Establishment

Name	Address	ID/FEI	Business Operations
Sypharma Pty Ltd		753786292	manufacture, pack, sterilize

Establishment

Name	Address	ID/FEI	Business Operations
New Zealand Salt Company Limited		594169799	api manufacture

Revised: 9/2018 MWI