VETONE- osmosol-r 7.4 sodium chloride,sodium gluconate,sodium acetate,potassium chloride and magnesium 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® OsmoSol™ –R 7.4
Multiple Electrolyte Injection Type 1, USP

STERILE NONPYROGENIC SOLUTION

For Animal Use Only

DESCRIPTION

VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) is a sterile, non–pyrogenic isotonic solution intended for fluid and electrolyte replenishment in single dose containers. May be administered intravenously using aseptic technique. It contains no antimicrobial agents· Discard any unused portion. The pH is adjusted with Sodium Hydroxide. Composition, osmolarity, pH and ionic concentration and caloric content are shown in Tabe 1·

Table 1

Composition (g/L)	Sodium Chloride	Sodium Gluconate	Sodium Acetate Trihydrate	Potassium Chloride	Magnesium Chloride
	5.26	5.02	3.68	0.37	0.30

Ionic Concentration (mEq/L)	Sodium	Potassium	Magnesium	Chloride	Acetate	Gluconate
	140	5	3	98	27	23

Osmolarity (mOsmol/L) (calc):294 mOsmol per litre

pH: 7·4 (limit 6.5 to 8.0)

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· It is capable of inducing diuresis depending on the clinical condition of the patient and produces a metabolic alkalinizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations·

INDICATIONS AND USAGE

VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) is indicated as a source of water and electrolytes for all species· It is also used as an alkalinizing agent.

VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) is compatible with blood or blood components. It may be administered prior to or following the infusion of blood through the same administration set (i·e., as a priming solution), added to or infused concurrently with blood components, or used as a diluent in the transfusion of packed erythrocytes·

CONTRAINDICATIONS

None known

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 OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, 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 and sodium retention.

VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, 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.

VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) should be used with great care in patients with metabolic or respiratory alkalosis. The administration of acetate or gluconate 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·

The intravenous administration of VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, 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 dilutional states is inversely proportional to the electrolyte concentrations of the injection. 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 functon, administration of VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) may result in sodium or potassium retention·

ADVERSE REACTIONS

Adverse reactions may occur due to the solution or the technique of administration including febrile response, infection at the site of injection or alergic 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 OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) should be used with caution. Excess administration may result in metabolic alkalosis·

Caution must be exercised in the administration of VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) to patients receiving corticosteroids or corticotropin·

Do not administer unless soution 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 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·

DOSAGE AND ADMINISTRATION

To be used as directed by a licensed veterinarian. The dosage of the VetOne OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) 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 veterinarian, 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 OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) in plastic container is available as follows:

Size (mL)	Item Code	NDC
1000	501205	13985-932-01
5000	501206	13985-932-05

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 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.

Made in Australia

Manufactured by:

Sypharma Pty Ltd

27 Healey Road Dandenong

Victoria 3175 Australia

Distributed by: MWI

Boise, ID 83705

www.VetOne.net

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Vetone OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) 1000ml

OsmoSol™-R 7.4

Multiple Electrolyte Injection Type I, USP

FOR ANIMAL USE ONLY

1000 mL (33.81 fl. oz.)

ACTIVE INGREDIENTS: EACH 100 mL CONTAINS SODIUM CHLORIDE 526 mg; SODIUM GLUCONATE 502 mg; SODIUM ACETATE TRIHYDRATE 368 mg; POTASSIUM CHLORIDE 37 mg; MAGNESIUM CHLORIDE 30 mg, IN WATER FOR INJECTION. MAY CONTAIN HCL OR NAOH FOR pH ADJUSTMENT.

mEq/LITER: SODIUM 140; POTASSIUM 5; MAGNESIUM 3; CHLORIDE 98; ACETATE 27; GLUCONATE 23.

OSMOLARITY: 294 mOsmo/LITER (CALC).

pH: 7.4 (6.5 – 8.0)

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 USING STRICT ASEPTIC TECHNIQUE. SEE PACKAGE INSERT.

CAUTION: STERILE NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. THIS IS A SINGLE DOSE UNIT. FOR INTRAVENOUS OR SUBCUTANEOUS USE. IT CONTAINS NO PRESERVATIVES. USE PROMPTLY UPON INITIAL ENTRY. IF ENTIRE CONTENTS ARE NOT USED, DISCARD UNUSED PORTION. SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY. DISCARD IF LEAKS ARE FOUND OR IF THE SOLUTION CONTAINS VISIBLE SOLID PARTICLES. DO NOT USE UNLESS SOLUTION IS CLEAR AND SEAL IS INTACT.

WARNING: 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 13985-932-01

VETone®

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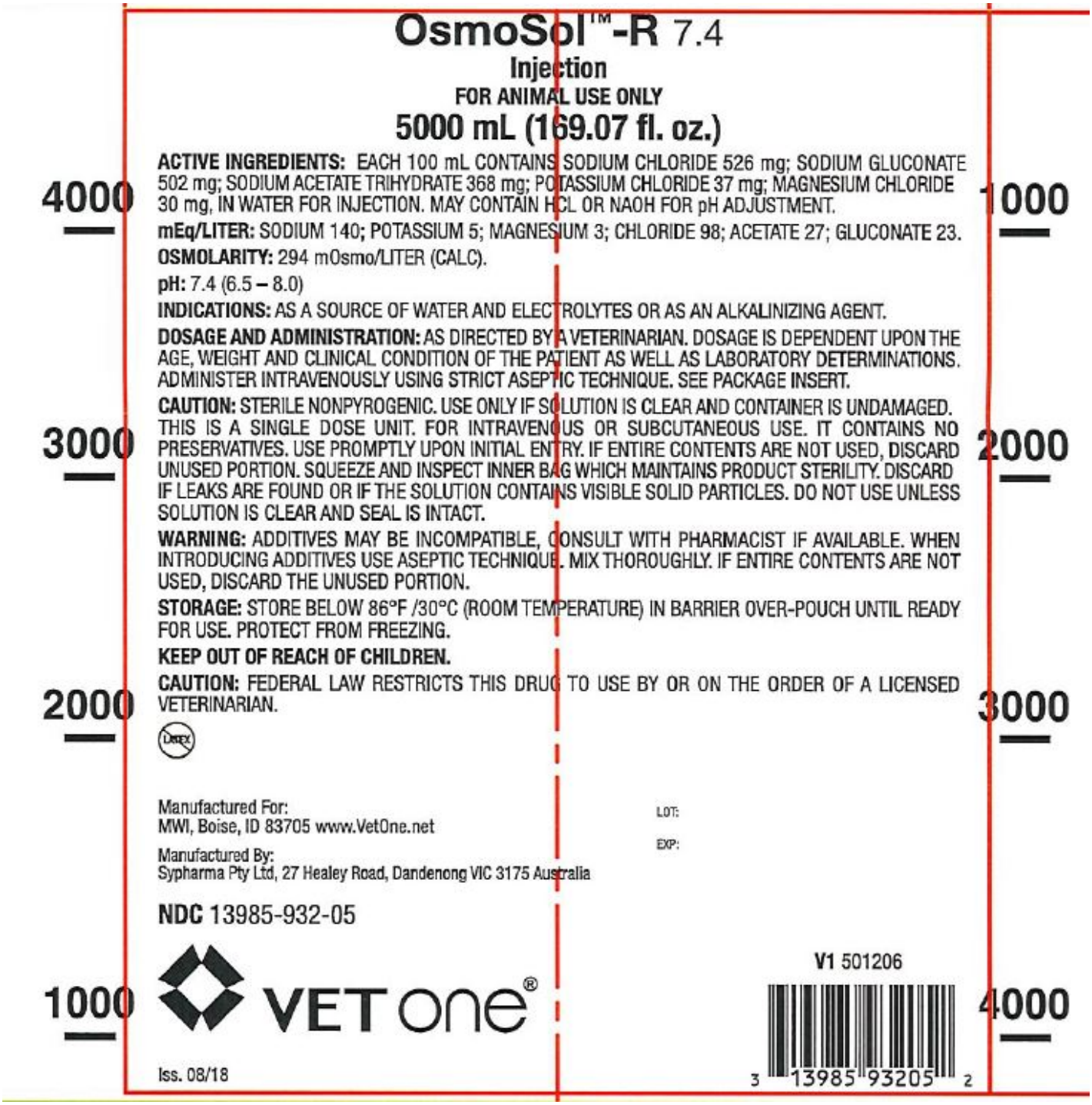
Iss. 05/18

Vetone OsmoSol–R 7·4 (Multiple Electrolyte Injection, Type 1, USP) 5000ml



VETONE

osmosol-r 7.4 sodium chloride,sodium gluconate,sodium acetate,potassium chloride and magnesium chloride injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:13985-932
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	526 mg in 100 mL
SODIUM GLUCONATE (UNII: R6Q3791S76) (SODIUM CATION - UNII:LYR4M0NH37, GLUCONIC ACID - UNII:R4R8J0Q44B)	SODIUM GLUCONATE	502 mg in 100 mL
SODIUM ACETATE (UNII: 4550K0SC9B) (SODIUM CATION - UNII:LYR4M0NH37, ACETATE ION - UNII:569DQM74SC)	SODIUM ACETATE	368 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	37 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CHLORIDE	30 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-932-01	12 in 1 CARTON		
1		1000 mL in 1 BAG		
2	NDC:13985-932-05	2 in 1 CARTON		
2		5000 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/13/2018	

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: 8/2018 MWI