**VETONE- saline solution 0.9% intravenous infusion 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.*

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**VetOne® Saline Solution 0.9% Intravenous Infusion**

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STERILE NONPYROGENIC SOLUTION

For Animal Use Only

**DESCRIPTION**

VetOne Saline Solution 0.9% Intravenous Infusion is a sterile, non-pyrogenic solution intended for water and electrolytes replenishment 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 are shown in Table 1

**Table 1**

| Composition (g/L) | Osmolarity (mOsmol/L) (calc) | pH | Ionic Concentration (mEq/L) | |
|---|---|---|---|---|
| Sodium Chloride NaCl | | | Sodium | Chloride |
| 9.0 | 308 | 5.5 (4.5 - 7) | 154 | 154 |

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

**CLINICAL PHARMACOLOGY**

VetOne Saline Solution 0.9% Intravenous Infusion is intended to restore water and electrolytes. It is capable of inducing diuresis, depending on the clinical condition of the patient.

## INDICATIONS AND USAGE

VetOne Saline Solution 0.9% Intravenous Infusion is indicated as a source of water and electrolytes.

## CONTRAINDICATIONS

None known

## WARNINGS

VetOne Saline Solution 0.9% Intravenous Infusion 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.

The intravenous administration of VetOne Saline Solution 0.9% Intravenous Infusion 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 VetOne Saline Solution 0.9% Intravenous Infusion may result in sodium retention.

## 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·

Caution must be exercised in the administration of VetOne Saline Solution 0.9% Intravenous Infusion to patients receiving corticosteroids or corticotrophin.

Do not administer unless solution is clear and seal is 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 discolouration 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 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 Saline Solution 0.9% Intravenous Infusion in plastic container is available as follows:

| Size (mL) | Item Code | NDC |
|---|---|---|
| 250 | 501210 | 13985-934-25 |
| 1000 | 501208 | 13985-934-01 |

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 silt 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 need 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 mixthoroughly.

**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 THS 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: MW

Boise, ID 83705

www.VetOne.net

ISS. 04/18

**VETONE SALINE SOLUTION 0·9% INJECTION 250ML**

# Saline Solution 0.9%

## FOR ANIMAL USE ONLY

## 250 mL (8.45 fl. oz.)

**ACTIVE INGREDIENTS:** EACH 100 mL CONTAINS SODIUM CHLORIDE 0.9 g, IN WATER FOR INJECTION.

**mEq/LITER:** SODIUM 154; CHLORIDE 154.

**OSMOLARITY:** 308 mOsmo/LITER. (CALC).

**INDICATIONS:** AS A SOURCE OF WATER AND ELECTROLYTES 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:** 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:** 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** 13985-934-25

VET one®

**V1** 501210

3 13985 93425 4

Iss. 05/18

**VETONE SALINE SOLUTION 0·9% INJECTION 1000ML**

# Saline Solution 0.9%

## FOR ANIMAL USE ONLY

## 1000 mL (33.81 fl. oz.)

**ACTIVE INGREDIENTS:** EACH 100 mL CONTAINS SODIUM CHLORIDE 0.9 g, IN WATER FOR INJECTION.

**mEq/LITER:** SODIUM 154; CHLORIDE 154.

**OSMOLARITY:** 308 mOsmo/LITER. (CALC).

**INDICATIONS:** AS A SOURCE OF WATER AND ELECTROLYTES 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:** 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:** 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:
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**NDC** 13985-934-01

VETone®

**V1** 501208

3 13985 93401 8

Iss. 05/18

**VETONE**

saline solution 0.9% intravenous infusion injection, solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | PRESCRIPTION ANIMAL DRUG | **Item Code (Source)** | NDC:13985-934 |
| **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 | 900 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:13985-934-25 | 24 in 1 CARTON | | |
| **1** | | 250 mL in 1 BAG | | |
| **2** | NDC:13985-934-01 | 12 in 1 CARTON | | |
| **2** | | 1000 mL in 1 BAG | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 08/09/2018 | |

## 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