VETERINARY VEDALYTE - sodium chloride, sodium gluconate, sodium acetate trihydrate, potassium chloride, magnesium chloride injection
Vedco, 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 VEDALYTE 7.4 Injection, USP

For Animal Use Only

Description

Veterinary VEDALYTE 7.4 Injection, USP is a sterile, nonpyrogenic isotonic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents or preservatives. Discard unused portion. The pH is adjusted with sodium hydroxide. Composition, osmolarity, pH, ionic concentration and caloric content are shown in Table 1:

Table 1: Veterinary VEDALYTE® 7.4 Injection, USP

Size mL	500	1000	3000	5000
Sodium Chloride, USP (NaCl) (mg/100mL)	526	526	526	526
Sodium Gluconate, USP ($C_6H_{11}NaO_7$) (mg/100mL)	502	502	502	502
Sodium Acetate Trihydrate, USP ($C_2H_3NaO_2 \cdot 3H_2O$) (mg/100mL)	368	368	368	368
Potassium Chloride, USP (KCl) (mg/100mL)	37	37	37	37
Magnesium Chloride, USP ($MgCl_2 \cdot 6H_2O$) (mg/100mL)	30	30	30	30
Osmolarity (mOsmol/L) (calc)	294	294	294	294
pH	7.4 (6.5 to 8.0)	7.4 (6.5 to 8.0)	7.4 (6.5 to 8.0)	7.4 (6.5 to 8.0)
Sodium Ionic Concentration (mEq/L)	140	140	140	140
Potassium Ionic Concentration (mEq/L)	5	5	5	5
Magnesium Ionic Concentration (mEq/L)	3	3	3	3
Chloride Ionic Concentration (mEq/L)	98	98	98	98
Acetate Ionic Concentration (mEq/L)	27	27	27	27
Gluconate Ionic Concentration (mEq/L)	23	23	23	23
Caloric Content (kcal/L)	21	21	21	21

Clinical Pharmacology

Veterinary VEDALYTE 7.4 Injection, USP administered intravenously has a value as a source of water, electrolytes and calories. Normal physiological osmolarity range is 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. It is capable of inducing diuresis, depending on the clinical condition of the patient.

Veterinary VEDALYTE 7.4 Injection, USP produces a metabolic alkalinilizing effect. Acetate and gluconate ions are metabolized ultimately to carbon dioxide and water, which requires consumption of hydrogen cations

Indications and Usage

Veterinary VEDALYTE 7.4 Injection, USP is indicated as a source of water and electrolytes or as an

alkalinizing agent

Veterinary VEDALYTE 7.4 Injection, 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 primary solution), added to or infused concurrently with blood components or used a diluent in the transfusion of packed erythrocytes. VEDALYTE 7.4 Injection, USP and 0.9% Sodium Chloride Injection, USP are equally compatible with blood or blood components

Contraindications

None Known

Warnings

Veterinary VEDALYTE 7.4 Injection, 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 with sodium retention.

Veterinary VEDALYTE 7.4 Injection, USP should be used with great care, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Veterinary VEDALYTE 7.4 Injection, 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 Veterinary VEDALYTE 7.4 Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional 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 lactated Ringer's Injection, USP may result in sodium or potassium retention.

Adverse Reaction

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.

VETERINARY VEDALYTE 7.4 Injection,USP must be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of VETERINARY VEDALYTE 7.4 Injection, USP 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 discoloration 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 judgment 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.

How Supplied

Veterinary VEDALYTE 7.4 Injection, USP in plastic container is available as follows:

How Supplied:

Veterinary VEDALYTE® 7.4 Injection, USP in plastic container is available as follows:

NDC Code	Item Number	Size (mL)	Product Name	PVC-Free
50989-892-16	VINV-B892-0500	500	Veterinary VEDALYTE® 7.4 Injection, USP	Yes*
50989-892-17	VINV-B892-1000	1000	Veterinary VEDALYTE® 7.4 Injection, USP	Yes*
50989-892-33	VINV-B892-3000	3000	Veterinary VEDALYTE® 7.4 Injection, USP	No**
50989-892-32	VINV-B892-5000	5000	Veterinary VEDALYTE® 7.4 Injection, USP	No**

Plastic Container:

*PVC Free, DEHP Free, Latex Free Bag.

** The plastic container is fabricated from a specially formulated polyvinyl chloride. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), upto 5 parts per million. However safety of the plastic has been confirmed in animals according to USP biological tests for plastic containers, as well as tissue culture toxicity studies.

Storage

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored in the moisture overwrap at room temperature (25°C/77°F); brief exposure up to (40°C/104°F) does not adversely affect the product.

Direction for use of plastic section

To Open

Tear overwrap down side 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 inner bag 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 protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

WARNING: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable 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 clamp on the administration set to stop flow to the patient.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable 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 (USA) restricts this drug to use by or on the order of a licensed veterinarian.

Manufactured for

Vedco, Inc.
5503 Corporate Dr.

St. Joseph, MO 64507 USA

Printed in El Salvador

For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Vedco, Inc. customer service at 1(888) 708-3326

Principal Display Panel

NDC 50989-892-16

BIOGALENIC VEDCO

VETERINARY VEDALYTE 7.4 INJECTION, USP

NDC 50989-892-16

BIOGALENIC VEDCO

VETERINARY VEDALYTE®
7.4 INJECTION, USP

Each 100 mL contains: 526 mg Sodium Chloride USP, 502 mg Sodium Gluconate USP, 368 mg Sodium Acetate Trihydrate USP, 37 mg Potassium Chloride USP, 30 mg Magnesium Chloride USP, pH Adjusted with Sodium Hydroxide, pH 7.4 (6.5 to 8.0). mEq/L: Sodium 140, Potassium 5, Magnesium 3, Chloride 98, Acetate 27, Gluconate 23. Osmorality: 294 mOsmol/L (Calc). Sterile Nonpyrogenic. Single Dose Container. Contains no antimicrobial agents or preservatives. Use solution promptly following initial entry. Additives may be incompatible. Consult with pharmacist if available. When introducing additives use aseptic technique. Mix thoroughly. Discard unused portion. Dosage: Intravenously as directed by a veterinarian. See package insert cautions. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found. Do not use unless solution is clear and seal is intact. Store unit in moisture barrier overwrap at room temperature (25°C/77°F) until ready to use. Avoid excessive heat.

For Animal Use Only

Keep out of Reach of Children

Caution: Federal Law (USA) restricts this drug to use by or on the order of a licensed veterinarian.

500 mL STERILE PVC LATEX

Manufactured for:

VEDCO

5503 Corporate Dr.
St. Joseph, MO 64507

Customer Service No.
1-888-708-3326

Made in El Salvador

NDC 50989-892-17

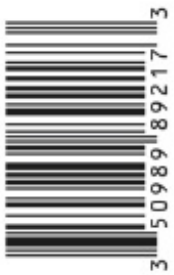
BIOGALENIC VEDCO

VETERINARY VEDALYTE 7.4 INJECTION, USP

NDC 50989-892-17

BIOGALENIC VEDCO

VETERINARY VEDALYTE®
7.4 INJECTION, USP



EACH 100 mL CONTAINS: 526 mg SODIUM CHLORIDE USP, 502 mg SODIUM GLUCONATE USP, 368 mg SODIUM ACETATE TRIHYDRATE USP, 37 mg POTASSIUM CHLORIDE USP, 30 mg MAGNESIUM CHLORIDE USP, pH ADJUSTED WITH SODIUM HYDROXIDE, pH 7.4 (6.5 TO 8.0). mEq/L: SODIUM 140, POTASSIUM 5, MAGNESIUM 3, CHLORIDE 98, ACETATE 27, GLUCONATE 23. OSMORALITY: 294 mOsmol/L (CALC). STERILE NONPYROGENIC. SINGLE DOSE CONTAINER. CONTAINS NO ANTIMICROBIAL AGENTS OR PRESERVATIVES. USE SOLUTION PROMPTLY FOLLOWING INITIAL ENTRY. ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST IF AVAILABLE. WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE. MIX THOROUGHLY. DISCARD UNUSED PORTION. DOSAGE: INTRAVENOUSLY AS DIRECTED BY A VETERINARIAN. SEE PACKAGE INSERT CAUTIONS. SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY. DISCARD IF LEAKS ARE FOUND. DO NOT USE UNLESS SOLUTION IS CLEAR AND SEAL IS INTACT. STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE. AVOID EXCESSIVE HEAT.

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

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

1000 mL

STERILE

MANUFACTURED FOR:
VEDCO
5503 CORPORATE DR.
ST. JOSEPH, MO 64507

CUSTOMER SERVICE NO.
1-888-708-3326

MADE IN EL SALVADOR

VETERINARY VEDALYTE

sodium chloride, sodium gluconate, sodium acetate trihydrate, potassium chloride, magnesium chloride injection

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:50989-892
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	526 mg in 100 mL
SODIUM GLUCONATE (UNII: R6Q3791S76) (GLUCONIC ACID - UNII:R4R8J0Q44B, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM GLUCONATE	502 mg in 100 mL
SODIUM ACETATE (UNII: 4550K0SC9B) (ACETATE ION - UNII:569DQM74SC, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM ACETATE	368 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	37 mg in 100 mL
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838, CHLORIDE ION - UNII:Q32ZN48698)	MAGNESIUM CHLORIDE	30 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50989-892-16	500 mL in 1 CONTAINER		
2	NDC:50989-892-17	1000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/12/2016	

Labeler - Vedco, Inc. (021634266)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Biogalenic SA de CV		851259507	api manufacture, manufacture

Revised: 10/2016 Vedco, Inc.