VETERINARY 5% DEXTROSE - dextrose injection, solution
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 5% dextrose for Injection, USP

For Animal Use Only

Description

5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment in single dose containers for intravenous administration. It contains no antimicrobial agents or preservatives. Discard unused portion. Composition, osmolarity, and ionic concentration are shown in Table 1:

TABLE 1

Veterinary 5% Dextrose Injection USP	
Size mL	1000
Dextrose Hydrous, USP ($C_6H_{12}O_6 \cdot H_2O$) (g/100mL)	5
Osmolarity (mOsmol/L) (calc)	252
pH	4.0 (3.2 to 6.5)
Caloric Content (kcal/L)	170

Clinical Pharmacology

5% Dextrose Injection, USP has value as a source of water and calories. It is capable of inducing diuresis, depending on the clinical condition of the patient.

Indications and Usage

5% Dextrose Injection, USP is indicated as a source of water and calories

Contraindications

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

Warnings

5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis

The intravenous administration of 5% Dextrose Injection, 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 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.

Excessive administration of dextrose injection may result in significant hypokalemia

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.

5% Dextrose Injection,USP must be used with caution in patients with overt or subclinical diabetes mellitus.

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 solutions for injections in plastic containers are intended for intravenous administration using sterile equipment and aseptic technique.

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. Discard unused portion.

Over Dosage

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 5% Dextrose Injection, USP in plastic container is available as follows:

NDC Code	Item Number	Size (mL)	Product Name
50989-896-17	VINV-B934-1000	1000	5% Dextrose Injection, USP

Plastic Container:

PVC Free, DEHP Free, Latex Free

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 (25ºC/77ºF); brief exposure up to (40ºC/104ºF) does not adversely affect the product.

Directions for use of plastic container

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 set.
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 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

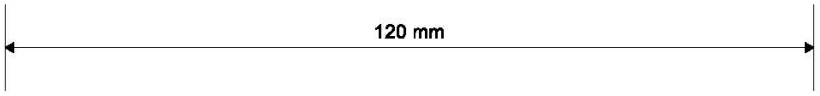
Principal Display Panel

NDC 50989-896-17

BIOGALENIC VEDCO

Veterinary 5% Dextrose for Injection, USP

Scale 100%, A4



NDC 50989-896-17

BIOGALENIC VEDCO

Veterinary 5% Dextrose for Injection, USP

1

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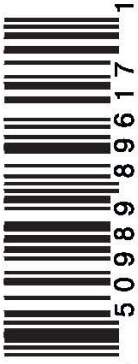

3

EACH 100 mL CONTAINS: 5 g DEXTROSE HYDROUS USP. pH 4.0 (3.2 TO 6.5). OSMOLARITY: 252 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.

4

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 ADMINISTER SIMULTANEOUSLY WITH BLOOD. 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.

5

6

FOR ANIMAL USE ONLY

7

KEEP OUT OF REACH OF CHILDREN

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

8

1000 mL

9

STERILE PVC LATEX

195 mm

MANUFACTURED FOR:

VEDCO

5503 CORPORATE DR.
ST. JOSEPH, MO 64507

MADE IN EL SALVADOR

CUSTOMER SERVICE NO.
1-888-708-3326

26 mm

LOT.0000000 EXP.00/0000

VINV-B934-1000

VETERINARY 5% DEXTROSE

dextrose injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:50989-896
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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50989-896-17	1000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/09/2016	

Labeler - Vedco, Inc. (021634266)

Establishment

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

Revised: 2/2016 Vedco, Inc.