

VETERINARY DEXTROSE- dextrose monohydrate injection, solution
Zoetis 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 Injection, USP

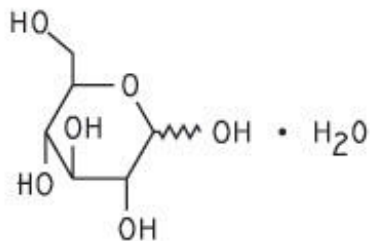
For Animal Use Only

Description

5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Discard unused portion. Composition, osmolarity, pH, and caloric content are shown in table 1.

Table 1

	Size (mL)	Composition (g/L)		Osmolarity (mOsmo/L) (calc)	pH	Caloric Content (kcal/L)
		Dextrose Hydrous, USP (C ₆ H ₁₂ O ₆ •H ₂ O)				
Veterinary 5% Dextrose Injection, USP	1000	50.00		252	4.0 (3.2 to 6.5)	170



D-Glucose monohydrate

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), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological test for plastic containers as well as by tissue culture toxicity studies.

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 may 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, overhydration, congested states, or pulmonary edema.

The risk of dilutive states is inversely proportional to the electrolyte concentrations 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 injections may result in significant hypokalemia.

Adverse Reactions

Reactions which may occur because of the injection 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 should 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 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 veterinarian, 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 overhydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings , Precautions and Adverse Events .

How Supplied

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

Size (mL)	Code
1000	2B8264

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

Directions for Use of plastic container

To Open

Tear overwrap down side at slit and remove solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. 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:

Zoetis Inc.

Kalamazoo, MI 49007

For customer service call (888) 963-8471

Printed in USA

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30603600

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Principal Display Panel

**Veterinary 5% Dextrose Injection USP
1000 ml**

**Veterinary
5% Dextrose Injection USP**

1000 mL

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 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 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

FOR ANIMAL USE ONLY

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

FOR CUSTOMER SERVICE CALL 888 963 8471

MANUFACTURED FOR
ZOETIS INC
KALAMAZOO MI 49007
MADE IN USA

30604700
2B8264

zoetis

Label for Veterinary Dextrose

VETERINARY DEXTROSE

dextrose monohydrate injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-4934
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	50 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-4934-1	1000 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		03/23/2011	

Labeler - Zoetis Inc. (828851555)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		189 326 168	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059 140 764	API MANUFACTURE, MANUFACTURE

Revised: 8/2016

Zoetis Inc.