

VETERINARY DEXTROSE AND SODIUM CHLORIDE- dextrose and sodium chloride 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 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP

For Animal Use Only

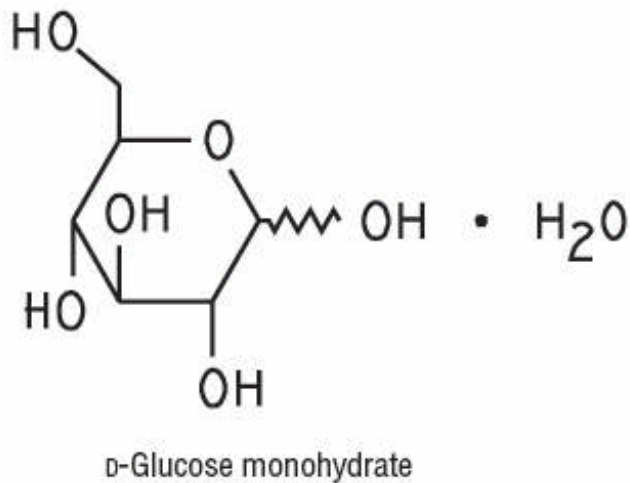
Description

2.5% Dextrose and 0.45% Sodium Chloride Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in single dose containers for intravenous administration. It contains no antimicrobial agents. Discard unused portion. Composition, osmolarity, pH, concentration and caloric content are shown in Table 1.

Table 1

	Size (mL)	Composition (g/L)		Osmolarity (mOsmol/L) (calc)	pH	Concentration (mEq/L)		Caloric Content (kcal/L)
		Dextrose Hydrated, USP (C ₆ H ₁₂ O ₆ •H ₂ O)	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
Veterinary 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	1000	25	4.5	280	4.5 (3.2 to 6.5)	77	77	85

Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (≥ 600 mOsmol/L) may cause vein damage.



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 tests for plastic containers as well as by tissue culture toxicity studies.

Clinical Pharmacology

2.5% Dextrose and 0.45% Sodium Chloride Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

Indications and Usage

2.5% Dextrose and 0.45% Sodium Chloride Injection, USP is indicated as a source of water, electrolytes, and calories.

Contraindications

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

Warnings

2.5% Dextrose and 0.45% Sodium Chloride 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.

2.5% Dextrose injections with low electrolyte concentrations should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

The intravenous administration of 2.5% Dextrose and 0.45% Sodium Chloride 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 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 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP may result in significant hypokalemia.

In patients with diminished renal function, administration of 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP 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 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

2.5% Dextrose and 0.45% Sodium Chloride 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

2.5% Dextrose and 0.45% Sodium Chloride Injection, USP in plastic container is supplied as follows:

Size (mL)	Code
1000	2B8224

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. 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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Principal Display Panel

Veterinary 2.5% Dextrose and

0.45% Sodium Chloride

Injection USP

1000 mL

**Veterinary 2.5% Dextrose and
0.45% Sodium Chloride
Injection USP**

1000 mL

EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
450 mg SODIUM CHLORIDE USP pH 4.5 (3.2 to 6.5) mEq/L
SODIUM 77 CHLORIDE 77 OsmOLARITY 280 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 PORTIONS 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

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

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ZOETIS INC
KALAMAZOO MI 49007

30804800
288224

MADE IN USA

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Label for Veterinary Dextrose and Sodium Chloride

VETERINARY DEXTROSE AND SODIUM CHLORIDE

dextrose and sodium chloride injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-4933
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	2.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8 X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	450 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-4933-1	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		059140764	API MANUFACTURE, MANUFACTURE

Revised: 8/2016

Zoetis Inc.