ALFA VETERINARY 5% DEXTROSE- 5% dextrose injection, solution
Laboratorios Alfa SRL

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.

DESCRIPTION

5% dextrose solution is sterile, non-pyrogenic for fluid and calorie replacement, and is supplied in single-dose containers for intravenous administration. Discard the unused portion. Does not contain antimicrobial agents.

Chemically, dextrose (glucose) is a monosaccharide containing an aldehyde group (an aldose). In water it exists primarily as a six membered hemi-acetal ring in equilibrium with a minor amount of the free aldehyde form and a five membered hemiacetal form. Dextrose used is either an anhydrous or monohydrate form.

The Plastic container, a semi-rigid bottle, is made of a low-density polyethylene which is a flexible and resistant material. No venting is necessary during infusion.

Table 1. Veterinary 5% Dextrose Injection, USP

Size (mL)	Composition (g/100 mL) Dextrose 1H2	*Osmolarity (mOsmol/L) (Calculated)	**pH**	Caloric Content (kcal/L)
100 250 500 1000	5.5	278	3.2-6.5	170

No venting is necessary during infusion.

CLINICAL PHARMACOLOGY

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

Glucose is a nutrient of the first order, provides 4.1 Kcal per gram and like all carbohydrates has the property of decreasing protein catabolism

INDICATIONS AND USAGE

5% dextrose solution is indicated as a source of water and calories. It is used to decrease the excessive pressure of spinal brain fluid, also as sclerosing to treat varicose veins and decrease intracranial pressure

WARNING

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

The intravenous administration of 5% Dextrose Injection 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 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.

The container label for these injections bears the statement: D**o not administer simultaneously with blood.**
Keep out of the reach of children.

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

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

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.

This is a hypotonic solution and as such should not be used for resuscitation.

Do not administer unless solution is clear and both seal and container are 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. Discard unused portion.

OVERDOSAGE

In an event of over hydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings, Precautions, and Adverse Reactions.

STORAGE

Store below 30°C (86°F).

PRECAUTION FOR USE OF THE BOTTLE

This is a single dose container and does not contain preservatives.

Use the solution immediately after the bottle is opened, discard the remaining one.
Squeeze and inspect the bottle, discard if leaks are found or if the solution contains visible and solid particles.

Do not administer simultaneously with blood.
Do not use it unless solution is clear, and seal is intact.

DIRECTIONS FOR USE PLASTIC CONTAINER:

This is a single dose container and does not contain preservatives. If leaks are found, discard solution as sterility may be impaired. Use the solution immediately after the bottle is opened, discard the remaining one. Discard unused portion. If supplemental medication is desired follow directions below:

Preparation and administration
1. Check for minute leaks by squeezing the container firmly. If leaks are found, discard solution as sterility may be impaired.
2. Suspend container from eyelet support.
3. Remove Plastic protector from ports area at the bottom of container.
4. Hold the bottle in vertical position and inset pyrogen free IV administration set in the outlet port. Use aseptic Technique

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 inlet 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 18 to 21 gauge needle, puncture inlet port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Mix solution and medication thoroughly.
6. 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.

PACKAGE INSERT

For Animal Use Only

ALFA VETERINARY 5% DEXTROSE INJECTION, USP
Dextrose Injection, solution
Laboratorios ALFA

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA.

5% Dextrose Injection, solution
For Animal Use Only
Sterile – Non-pyrogenic solution

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COMPOSITION:

Table 1. Veterinary 5% Dextrose Injection, USP

Size (mL)	Composition (g/100 mL)	*Osmolarity (mOsmol/L) (Calculated)	**pH**	Caloric Content (kcal/L)
	Dextrose 1H2O			
100	5.5	278	3.2-6.5	170
250				
500				
1000				

No venting is necessary during infusion.

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

Glucose is a nutrient of the first order, provides 4.1 Kcal per gram and like all carbohydrates has the property of decreasing protein catabolism

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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.

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OVERDOSAGE:
In an event of over hydration or solute overload, re-evaluate the patient and institute appropriate corrective measures. See Warnings, Precautions, and Adverse Reactions.

STORAGE:
Store below 30ºC (86ºF).

ROUTE OF ADMINISTRATION:
Intravenous

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5. Mix solution and medication thoroughly.
6. Return container to in use position and continue administration.

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Manfactured by:
LABORATORIOS ALFA S.R.L.,
Santo Domingo, Dominican Republic
Revised OCtober 2019

Veterinary 5% Dextrose Injection,

NDC: :72483-200-10 1000 mL 5% Dextrose

NDC: 72483-200-05 500 mL 5% Dextrose

NDC: 72483-200-25 250 mL 5% Dextrose

NDC: 72483-200-01 100 mL 5% Dextrose

4.2 CM

4.8 CM

NDC 72483-200-25 250 mL

DEXTROSE 5%
INJECTION, USP
VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION
KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL USE ONLY

COMPOSITION:
Each 100 mL contains:
Dextrose Monohydrate, USP.....5.5 g
Equivalent to 5g of Dextrose
Water for injection USP.....q.s.
Total osmolarity is 278 milliosmoles per liter (calc).
pH 3.2-6.5

INDICATIONS:
Veterinary Dextrose Injection, USP is indicated as a source of water and calories.

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.

CAUTION: This is a single dose container and contains no preservatives. Use solution promptly following initial entry, discard unused portion.

Lot.:

Exp.:

Squeeze and inspect the bottle, 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. Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNING:
Additives may be incompatible. Consult a pharmacist if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

STORAGE:
Store below 30°C (86 °F).

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

TAKE TIME  OBSERVE LABEL DIRECTIONS

7 468999 196822

Manufactured by:
Laboratorios ALFA, S.R.L.
Santo Domingo
Dominican Republic
www.laboratoriosalfa.com
1-809-544-0222

102 MM

37 MM

2.5"

4.68"

NDC 72483-200-05

500 mL

DEXTROSE 5%

INJECTION, USP

VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION
KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL USE ONLY

COMPOSITION: Each 100 mL contains:
Dextrose Monohydrate, USP.....5.5 g
Equivalent to 5g of Dextrose
Water for injection USP.....q.s.
Total osmolarity is 278 milliosmoles per liter (calc). pH 3.2-6.5

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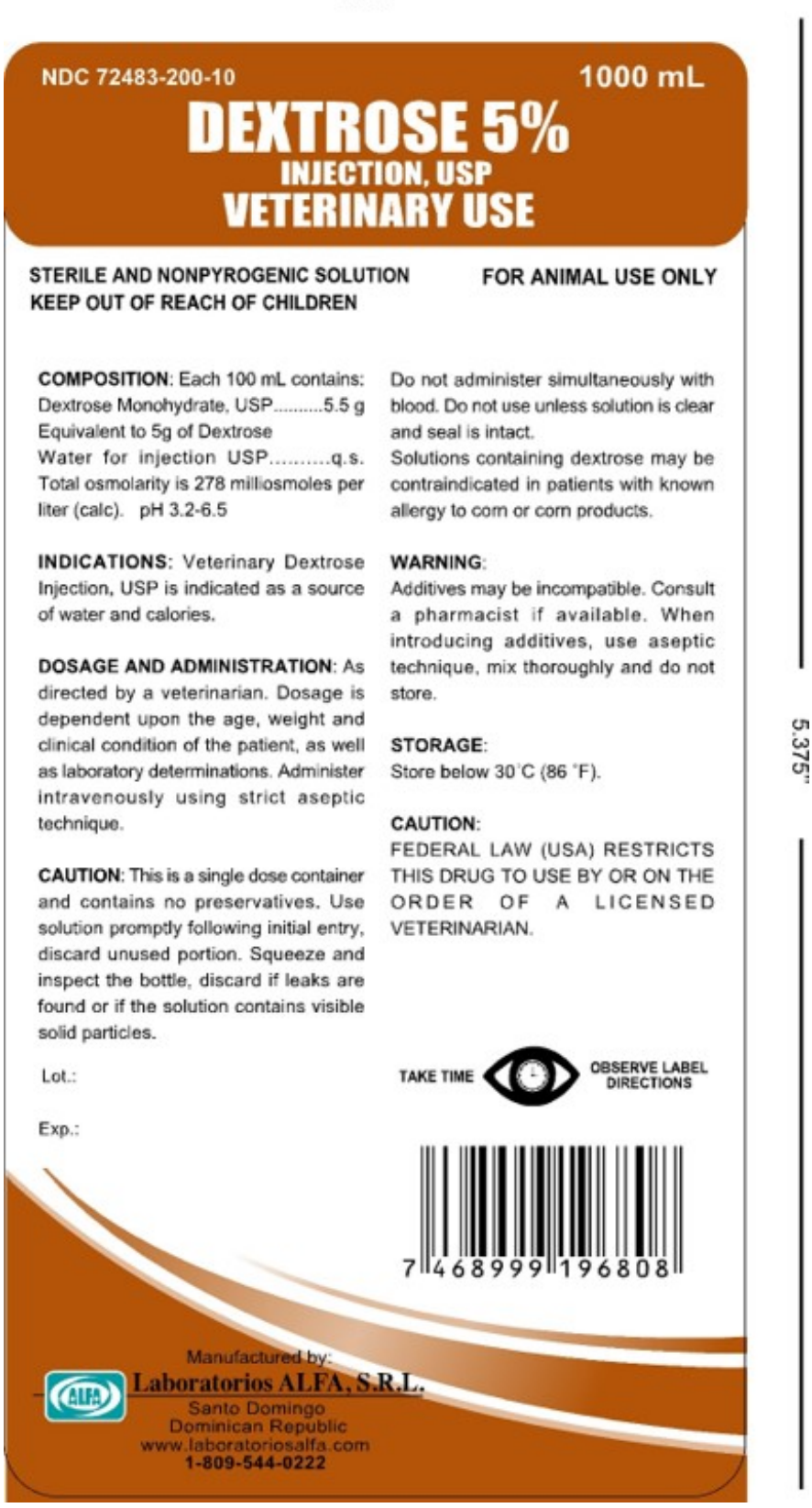
7 468999 196815

Manufactured by:
Laboratorios ALFA, S.R.L.
Santo Domingo
Dominican Republic
www.laboratoriosalfa.com
1-809-544-0222



ALFA VETERINARY 5% DEXTROSE

5% dextrose injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:72483-200

Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5000 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:72483-200-10	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:72483-200-05	500 mL in 1 BOTTLE, PLASTIC		
3	NDC:72483-200-25	250 mL in 1 BOTTLE, PLASTIC		
4	NDC:72483-200-01	100 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/14/2019	

Labeler - Laboratorios Alfa SRL (815941244)

Revised: 2/2020 Laboratorios Alfa SRL