

ALFA VETERINARY 10% DEXTROSE- 10% 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

10% 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 10% Dextrose Injection, USP

Size (mL)	Composition (g/100 mL) Dextrose 1H2O	*Osmolarity (mOsmol/L) (Calculated)	pH	Caloric Content (kcal/L)
100				
250				
500	11.0	3.2-6.5	3.2-6.5	340
1000				

No venting is necessary during infusion.

CLINICAL PHARMACOLOGY

10% Dextrose 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 4.1Kcal per gram and like all carbohydrates has the property of decreasing catabolism.

INDICATIONS AND USAGE

10% dextrose solution has value as a source of water and calories. It is used to decrease the excessive pressure of spinal brain fluid, also a sclerosing to treat varicose veins and decrease intracranial pressure.

undefined

Veterinary 10% Dextrose Injection 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 10% 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: **Do 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 10% 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.

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 10% 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.

10% Dextrose Injection
For Animal Use Only
Sterile-Non-pyrogenic

DESCRIPTION:

10% 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 10% Dextrose Injection, USP

Size (mL)	Composition (g/100 mL)	*Osmolarity (mOsmol/L) (Calculated)	pH	Caloric Content (kcal/L)
	Dextrose 1H ₂ O			
100	11.0	556	3.2-6.5	340
250				
500				
1000				

No venting is necessary during infusion.

CLINICAL PHARMACOLOGY:

Veterinary 10% 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.

PRINCIPAL DISPLAY PANEL

Veterinary 10% Dextrose Injection,

NDC: 72483-201-10 1000 mL 10% Dextrose

NDC: 72483-201-05 500 mL 10% Dextrose

NDC: 72483-201-25 250 mL 10% Dextrose

NDC: 72483-201-02 100 mL 10% Dextrose

4.2 CM

4.8 CM

NDC 72483-201-01 100 mL

DEXTROSE 10% INJECTION, USP VETERINARY USE

COMPOSITION: Each 100 mL contains: Dextrose Monohydrate, USP...11 g Equivalent to 10g of Dextrose Water for injection USP.....q.s. Total osmolarity is 556 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.
Lot:
Exp.:

Use solution promptly following initial entry, discard unused portion. 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 196877

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

NDC 72483-201-25

250 mL

DEXTROSE 10% 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.....11 g
Equivalent to 10g of Dextrose
Water for Injection
USP.....q.s.
Total osmolarity is 556
milliosmoles per liter (calc).
pH 3.2-6.5

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.

INDICATIONS:

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

WARNING:

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

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.

STORAGE:

Store below 30°C (86 °F).

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

CAUTION:

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

Lot.:

Exp.:



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102 MM

WW ZC

2.5"

NDC 72483-201-05

500 mL

DEXTROSE 10%

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 11 g
Equivalent to 10g of Dextrose
Water for injection USP q.s.
Total osmolarity is 556 milliosmoles per
liter (calc). pH 3.2-6.5

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.

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

WARNING:

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

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.

STORAGE:

Store below 30°C (86°F).

CAUTION: This is a single dose
container and contains no preservatives.
Use solution promptly following initial
entry, discard unused portion. Squeeze
and inspect the bottle, discard if leaks
are found or if the solution contains visible
solid particles.

CAUTION:

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

Lot.:

TAKE TIME  OBSERVE LABEL
DIRECTIONS

Exp.:



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Dominican Republic
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1-809-544-0222

4.68"

NDC 72483-201-10
1000 mL

DEXTROSE 10%

INJECTION, USP VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

COMPOSITION: Each 100 mL contains:
Dextrose Monohydrate, USP.....11 g
Equivalent to 10g of Dextrose
Water for injection USP.....q.s.
Total osmolarity is 556 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. Squeeze and
inspect the bottle, discard if leaks are
found or if the solution contains visible
solid particles.

Lot.:
Exp.:


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 196853

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

5.375"

ALFA VETERINARY 10% DEXTROSE

10% dextrose injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:72483-201
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7R0OK)		DEXTROSE MONOHYDRATE	10 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:72483-201-10	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:72483-201-05	500 mL in 1 BOTTLE, PLASTIC		
3	NDC:72483-201-25	250 mL in 1 BOTTLE, PLASTIC		
4	NDC:72483-201-01	100 mL in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
unapproved drug other			11/16/2019	

Labeler - Laboratorios Alfa SRL (815941244)

Registrant - JMM Services (003488666)

Revised: 2/2024

Laboratorios Alfa SRL