ALFA VETERINARY DEXTROSE AND SODIUM CHLORIDE- dextrose and sodium chloride 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

Veterinary 5% dextrose in 0.9% Sodium Chloride Injection, USP is a sterile, non-pyrogenic solution for fluid replenishment in single dose containers for intravenous administration. Discard unused portion. It contains no antimicrobial agents.

Table 1. Veterinary 5% Dextrose in 9% Sodium Chloride Injection, USP

Size (mL)	Composition (g/ 100mL)		*Osmolarity	**pH**	Concentration (mEq/L)		Caloric Content (kcal/L)
	Dextrose 1H2O	Sodium Chloride, USP (NaCl)	(mOsmol/L) (Calculated)		Sodium	Chloride	
100 250 500 1000	5.5	0.9	586	3.2-6.5	154	154	170

No venting is necessary during infusion.

CLINICAL PHARMACOLOGY

Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP has value as a source of water, electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Veterinary 5% Dextrose in 0.9% Sodium Chloride, USP is indicated as a source of water, electroytes and calories.

CONTRAINDICATIONS

Solutions containing 5% Dextrose in 0.9% Sodium Chloride Injection, USP may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

Excessive administration of 5% Dextrose in 0.9% Sodium Chloride Injection, USP may result in significant hypokalemia.

Veterinary 5% Dextrose in 0.9% 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.

Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP should not be administered simultaneously with blood through the same administration set because of the possibility of pseudo agglutination or hemolysis.

The container label for these injections bears the statement: **Do not administer simultaneously with blood.**

The intravenous administration of veterinary 5% Dextrose in 0.9% Sodium Chloride 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 dilutive 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.

In patients with diminished renal function, administration of veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP may result in sodium retention proportional to the electrolyte concentrations of the injections.

Keep out of the reach of children.

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

5% Dextrose in 0.9% Sodium Chloride Injection, USP should be used with caution in patients with 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.

Caution must be exercised in the administration of veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotrophin.

Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP should be used with caution in patients with known subclinical or overt diabetes mellitus.

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 discolorations 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 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.

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).

PRECAUTION FOR USE OF THE BOTTLE

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:

Do not administer simultaneously with blood.
Do not use it unless solution is clear and seal is intact, the solution containing dextrose may be contraindicated in patients with a known allergy to corn or corn products.

Preparation and administration

Check for minute leaks by squeezing the container firmly. If leaks are found, discard solution as sterility may be impaired.
Suspend container from eyelet support.
Remove Plastic protector from ports area at the bottom of container.
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. Return container to in-use position and continue administration. 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 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 IN 0.9% SODIUM CHLORIDE
Dextrose and sodium chloride 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 in 0.9% Sodium chloride
For Animal Use Only
Sterile – Non-pyrogenic solution

DESCRIPTION:
Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP is a sterile, non-pyrogenic solution for fluid replenishment in single dose containers for intravenous administration. Discard unused portion. It contains no antimicrobial agents.

COMPOSITION:

Table 1. Veterinary 5% Dextrose in 9% Sodium Chloride Injection, USP

Size (mL)	Composition (g/100 mL)		*Osmolarity (mOsmol/L) (Calculated)	**pH**	Concentration (mEq/L)		Caloric Content (kcal/L)
	Dextrose $1H_2O$	Sodium Chloride, USP (NaCl)			Sodium	Chloride	
100	5.5	0.9	586	3.2-6.5	154	154	170
250							
500							
1000							

No venting is necessary during infusion.

CLINICAL PHARMACOLOGY:
Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP has value as a source of water, electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE:
Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP is indicated as a source of water, electrolytes and calories.

CONTRAINDICATIONS:
Solutions containing 5% Dextrose in 0.9% Sodium Chloride Injection, USP may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS:
Excessive administration of 5% Dextrose in 0.9% Sodium Chloride Injection, USP may result in significant hypokalemia.

Veterinary 5% Dextrose in 0.9% 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.

Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP should not be administered simultaneously with blood through the same administration set because of the possibility of pseudo agglutination or hemolysis.

The container label for these injections bears the statement: **Do not administer simultaneously with blood.**

The intravenous administration of veterinary 5% Dextrose in 0.9% Sodium Chloride 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 dilutive 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.

In patients with diminished renal function, administration of veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP may result in sodium retention proportional to the electrolyte concentrations of the injections.

Keep out of the reach of children.

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:
5% Dextrose in 0.9% Sodium Chloride Injection, USP should be used with caution in patients with 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.

Caution must be exercised in the administration of veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotrophin.

Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP should be used with caution in patients with known subclinical or overt diabetes mellitus.

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 discolorations 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 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.

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.

PACKAGING:
VET DEXTROSE 5% IN 0.9% SODIUM CHLORIDE 1000 ML....**NDC: 72483-205-10**
VET DEXTROSE 5% IN 0.9% SODIUM CHLORIDE 500 ML.....**NDC: 72483-205-05**
VET DEXTROSE 5% IN 0.9% SODIUM CHLORIDE 250 ML.....**NDC: 72483-205-25**
VET DEXTROSE 5% IN 0.9% SODIUM CHLORIDE 100 ML.....**NDC: 72483-205-01**

STORAGE:
Store below 30ºC (86ºF).

ROUTE OF ADMINISTRATION:
Intravenous
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 a minute for 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. Return container to in-use position and continue administration. 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 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.

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

Revised March 2019

PRINCIPAL DISPLAY PANEL

Dextrox 5% in 0.9% Sodium Chloride Injection, USP

Veterinary Use

Sterile and NonProgenic Solution

Keep out of reach of Children.

For Animal Use Only.

Take Time - Observe label directions

Manufactured by:

Laboratorios Alfa, SRL

Santo Domingo

Domincan Republic

www.laboratoriosalfa.com

+1-809-544-0222

4.2 CM

4.8 CM

NDC 72483-205-01

100 mL

DEXTROSE 5% IN 0.9% SODIUM CHLORIDE
INJECTION, USP
VETERINARY USE

COMPOSITION: Each 100 mL contains:
Sodium Chloride, USP.....0.9 g
Dextrose 1H2O USP.....5.5 g
Equivalent to 5g of Dextrose
Water for injection USP q.s.....100 mL

Milliequivalents per liter:
- Na+ 154.0 mEq/L
- Cl- 154.0 mEq/L

Total osmolarity is 586.0 milliosmoles per liter (calc). pH 3.2-6.5

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

Lote:

Exp.:

TAKE TIME  OBSERVE LABEL DIRECTIONS

7 468999 196914

Manufactured by:

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

NDC 72483-205-25

250 mL

DEXTROSE 5% IN 0.9% SODIUM CHLORIDE
INJECTION, USP
VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION
KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL USE ONLY

COMPOSITION:
Each 100 mL contains:
Sodium Chloride, USP.....0.9 g
Dextrose 1H2O USP.....5.5 g
Equivalent to 5g of Dextrose
Water for injection USP q.s.....100 mL

Milliequivalents per liter:
- Na+ 154.0 mEq/L
- Cl- 154.0 mEq/L

Total osmolarity is 586.0 milliosmoles per liter (calc).
pH 3.2-6.5

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

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.

102 MM

Exp.:

TAKE TIME  OBSERVE LABEL DIRECTIONS

7 468999 196907

Manufactured by:

Laboratorios ALFA, S.R.L.

Santo Domingo
Dominican Republic
www.laboratoriosalfa.com
1-809-544-0222

37 MM

2.5”

NDC 72483-205-05 **500 mL**

DEXTROSE 5% IN 0.9% SODIUM CHLORIDE
INJECTION, USP
VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION
KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL USE ONLY

COMPOSITION:
Each 100 mL contains:
Sodium Chloride, USP.....0.9 g
Dextrose 1H2O USP.....5.5 g
Equivalent to 5g of Dextrose
Water for injection USP q.s.....100 mL

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

Milliequivalents per liter:
- Na+ 154.0 mEq/L
- Cl- 154.0 mEq/L

Total osmolarity is 586.0 milliosmoles per liter (calc). pH 3.2-6.5

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

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.

7 468999 196891

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

4.68"

2.75"

NDC 72483-205-10 1000 mL

DEXTROSE 5% IN 0.9% SODIUM CHLORIDE
INJECTION, USP
VETERINARY USE

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

COMPOSITION:
Each 100 mL contains:
Sodium Chloride, USP.....0.9 g
Dextrose 1H2O USP.....5.5 g
Equivalent to 5g of Dextrose
Water for injection USP q.s.....100 mL

Milliequivalents per liter:
- Na+ 154.0 mEq/L
- Cl- 154.0 mEq/L

Total osmolarity is 586.0 milliosmoles per liter (calc). pH 3.2-6.5

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

Lot.:

Exp.:

TAKE TIME  OBSERVE LABEL DIRECTIONS

7 468999 196884

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

5.375"

ALFA VETERINARY DEXTROSE AND SODIUM CHLORIDE

dextrose and sodium chloride injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:72483-205
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	5.5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	900 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:72483-205-10	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:72483-205-05	500 mL in 1 BOTTLE, PLASTIC		
3	NDC:72483-205-25	250 mL in 1 BOTTLE, PLASTIC		
4	NDC:72483-205-01	100 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/25/2019	

Labeler - Laboratorios Alfa SRL (815941244)

Registrant - JMM Services (003488666)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Alfa SRL		817468920	api manufacture

Revised: 3/2025 Laboratorios Alfa SRL