

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) | Sodium (mOsmol/L) (Calculated) | | Sodium Chloride | | |
| 100 | | | | | | | |
| 250 | | | | | | | |
| 500 | 5.5 | 0.9 | 586 | 3.2-6.5 | 154 | 154 | 170 |
| 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, 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.

STORAGE

Store below 30°C (86°F).

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, USP
Dextrose and Sodium Chloride injection, solution
Laboratorios ALFA



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

5% Dextrose in 0.9% Sodium Chloride Injection I For Animal Use Only I Sterile-Non-pyrogenic

ROUTE OF ADMINISTRATION:

- Intravenous

DESCRIPTION:

5% Dextrose in 0.9% Sodium Chloride 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. Composition, osmolarity, pH, and caloric content are shown in Table 1.

Glucose (**dextrose**) is a monosaccharide sugar that is obtained by acid hydrolysis from corn starch. 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 is used either an anhydrous or monohydrate form.

Table 1. Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP

| Size (mL) | Composition (g/100 mL) | | *Osmolarity (mOsmol/L) (Calculated) | pH | Concentration (mEq/L) | | Caloric Content (kcal/L) |
|---------------|----------------------------|-----------------------------|-------------------------------------|---------|-----------------------|----------|--------------------------|
| | Dextrose 1H ₂ O | Sodium Chloride, USP (NaCl) | | | Sodium | Chloride | |
| Bottle | | | | | | | |
| 100 | 5.5 | 0.9 | 586 | 3.2-6.5 | 154 | 154 | 170 |
| 250 | | | | | | | |
| 500 | | | | | | | |
| 1000 | | | | | | | |
| Bag | | | | | | | |
| 100 | 5.5 | 0.9 | 586 | 3.2-6.5 | 154 | 154 | 170 |
| 250 | | | | | | | |
| 500 | | | | | | | |
| 1000 | | | | | | | |
| 3000 | | | | | | | |
| 5000 | | | | | | | |

The **plastic container**, a semi-rigid bottle, is made of a low-density polyethylene (LDPE) resin which is a flexible and resistant material that provides an excellent compatibility with a maximum number of pharmaceuticals, reducing the risk of interactions. No venting is necessary during infusion.

The **flexible bag** sizes 3000mL – 5000mL are made from polyvinyl chloride (PVC) and sizes 100mL – 1000mL are made of polypropylene (PP), which are both a flexible and resistant materials that provide an excellent compatibility with a maximum number of pharmaceuticals, reducing the risk of interactions. No venting is necessary during infusion.

ALFA VETERINARY 5% DEXTROSE IN 0.9% SODIUM CHLORIDE, USP
Dextrose and Sodium Chloride injection, solution
Laboratorios ALFA



CLINICAL PHARMACOLOGY:

Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP solution has value as a source of water, electrolytes, and calories. It may induce diuresis depending on the clinical condition of the patient.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration. Dextrose provides a source of calories.

Dextrose (glucose) is readily metabolized, may decrease losses of body protein and nitrogen, promotes glycogen deposition, and decreases or prevents ketosis if sufficient doses are provided. **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:

Veterinary 5% Dextrose in 0.9% Sodium Chloride Injection, USP solution is indicated as a source of electrolytes, calories, and water for hydration.

CONTRAINDICATIONS:

- These solutions are contraindicated where the administration of sodium or chloride could be clinically detrimental
- Solutions containing dextrose may be contraindicated in patients with known allergies to corn or corn products

WARNINGS:

- 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
- Solutions containing sodium ions 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 is sodium retention with edema. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.
- 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.
- Infusion of isotonic (0.9%) sodium chloride during or immediately after surgery may result in excessive sodium retention. Use the patient's circulatory system status as a guide.
- The intravenous administration of Veterinary 5% Dextrose in 0.9% Sodium Chloride solution 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

ALFA VETERINARY 5% DEXTROSE IN 0.9% SODIUM CHLORIDE, USP
Dextrose and Sodium Chloride injection, solution
Laboratorios ALFA



WARNINGS: (Cont.)

- 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. Serum potassium levels should be maintained, and potassium supplemented as required.

The container label for these injections bears the statement:

- **Do not administer simultaneously with blood**
- **Keep out of the reach of children**

PRECAUTIONS:

- These solutions should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation.
- Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.
- Additional essential electrolytes, minerals and vitamins should be supplied as needed.
- Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients. Care should be exercised in administering solutions containing sodium to patients with renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.
- Infusion of more than one liter of isotonic (0.9%) sodium chloride per day may supply more sodium and chloride than normally found in serum, and can exceed normal tolerance, resulting in hypernatremia; this may also cause a loss of bicarbonate ions, resulting in an acidifying effect.
- Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.
- Hypokalemia may develop during parenteral administration of hypertonic dextrose solutions. Sufficient amounts of potassium should be added to dextrose solutions administered to fasting patients with good renal function, especially those on digitalis therapy.
- To minimize the risk of possible incompatibilities arising from mixing any of these solutions with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.
- Do not connect the plastic container in series in order to avoid air embolism.
- If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result. These solutions are intended for intravenous administration using sterile equipment. It is recommended that the intravenous administration apparatus be replaced at least once every 24 hours.
- This is a hypotonic solution and as such should not be used for resuscitation
- **Do not administer unless a solution is clear, and both seal and container are intact**

ADVERSE REACTIONS:

- Reactions that 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

ALFA VETERINARY 5% DEXTROSE IN 0.9% SODIUM CHLORIDE, USP
Dextrose and Sodium Chloride injection, solution
Laboratorios ALFA



ADVERSE REACTIONS: (cont.)

- 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

OVERDOSAGE:

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

DOSAGE AND ADMINISTRATION:

- **Do not administer** unless the solution is clear, and the seal is intact
- 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
- This product should be warmed to body temperature and administered slowly.
- Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with a veterinarian, if available.
- If, in the informed judgment of the veterinarian, it is deemed advisable to introduce additives, use an aseptic technique. Mix thoroughly when additives have been introduced.
- **Do not store any unused portion of the solution containing additives.** Discard unused portion.

HOW SUPPLIED:

Veterinary 5% Dextrose in 0.9% Sodium Chloride, USP (Injectable) solution is available in the following sizes:

BOTTLES

| | |
|--|------------------------------------|
| VET Dextrose 5% in 0.09 Sodium Chloride, 1000 mL | <u>NDC#</u> 72483-205-10 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 500 mL | 72483-205-05 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 250 mL | 72483-205-25 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 100 mL | 72483-205-01 |

BAGS

| | |
|--|------------------------------------|
| VET Dextrose 5% in 0.09 Sodium Chloride, 5000 mL | <u>NDC#</u> 72483-205-02 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 3000 mL | 72483-205-03 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 1000 mL | 72483-205-04 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 500 mL | 72483-205-06 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 250 mL | 72483-205-07 |
| VET Dextrose 5% in 0.09 Sodium Chloride, 100 mL | 72483-205-08 |

ALFA VETERINARY 5% DEXTROSE IN 0.9% SODIUM CHLORIDE, USP
Dextrose and Sodium Chloride injection, solution
Laboratorios ALFA



DIRECTIONS FOR USE OF PLASTIC BOTTLE:

To Open:

Remove the overwrap seal over the bottle cap. Visually inspect the container for leaks. If leaks or the seal is torn, broken, or missing, discard the solution as sterility may be impaired. Use the solution immediately

DIRECTIONS FOR USE OF PLASTIC BOTTLE: (Cont.)

after the bottle is opened. Discard unused portion. If supplemental medication is desired, follow the “**To Add Medication**” directions below.

Preparation and Administration

1. This is a **single-dose** container and does not contain preservatives.
2. Suspend the container from the eyelet support.
3. Remove the Plastic protector from the outlet port area at the bottom of the container.
4. Hold the bottle in a vertical position and inset pyrogen-free IV administration set in the outlet port. Use aseptic Technique.

DIRECTIONS FOR USE OF FLEXIBLE BAGS:

To Open:

Remove the overwrap downside at the slit and remove the solution container. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard the 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 the inner bag firmly. If leaks are found, discard the solution as sterility may be impaired. If supplemental medication is desired, follow the “**To Add Medication**” directions below.

Preparation and Administration

1. This is a **single-dose** container and does not contain preservatives.
2. Suspend the container from the eyelet support.
3. Remove the protector from the outlet port area at the bottom of the container.
4. Hold the bag in a 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 a syringe with a 18-to-21-gauge needle, puncture the inlet port and inject.
3. Mix the 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 the clamp on the set.
2. Prepare medication site.
3. Using a syringe with a 18-to-21-gauge needle, puncture the inlet port and inject.

ALFA VETERINARY 5% DEXTROSE IN 0.9% SODIUM CHLORIDE, USP
Dextrose and Sodium Chloride injection, solution
Laboratorios ALFA



4. Remove the container from the IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while the container is in the upright position.
6. Mix the solution and medication thoroughly.
7. Return container to in-use position and continue administration.

STORAGE:

- Store at room temperature 25°C (77°F)

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

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Dextrose 5% in 0.9% Sodium Chloride Injection, USP

For Veterinary Use Only

Dextrose 5% in 0.9% Sodium Chloride 100 mL NDC 72483-205-01

Dextrose 5% in 0.9% Sodium Chloride 250 mL NDC 72483-205-25

Dextrose 5% in 0.9% Sodium Chloride 500 mL NDC 72483-205-05

Dextrose 5% in 0.9% Sodium Chloride 1000 mL NDC 72483-205-10

NDC 72483-205-01 100 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

FOR VETERINARY USE ONLY

For Intravenous Infusion.
Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP, pH 3.2-6.5, mEq/L: 154 Sodium, 154 Chloride, Osmolarity: 586 mOsmol/L (calc).

INDICATIONS: As a source of water, electrolytes and calories.

DOSAGE AND ADMINISTRATION:
As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations. Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened. Discard unused portion.

Lote:
Exp.:

CAUTIONS: This is a single-dose container and does not contain preservatives. Squeeze and inspect bottle before use, discard if leaks are found or if the solution contains solid particles. **Do not administer** unless solution is clear, and seal is intact.

WARNINGS: Additives may be incompatible. Consult with a veterinarian, if available. When introducing additives, use an aseptic technique. Mix thoroughly. **Do not administer** simultaneously with blood.

KEEP OUT OF REACH OF CHILDREN.

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.

Mfg by: Laboratorios Alfa S.R.L., Av. República de Colombia KM 13, Santo Domingo Oeste, Santo Domingo 10701, Dominican Republic.
Toll-Free: +1-800-969-0581 / www.laboratoriosalfa.com
Made in Dominican Republic



7 468999 196914

NDC 72483-205-25 250 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

FOR VETERINARY USE ONLY

For Intravenous Infusion.
Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP, pH 3.2-6.5, mEq/L: 154 Sodium, 154 Chloride, Osmolarity: 586 mOsmol/L (calc).

Squeeze and inspect bottle before use, discard if leaks are found or if the solution contains solid particles. **Do not administer** unless solution is clear, and seal is intact.

INDICATIONS:

As a source of water, electrolytes and calories.

DOSAGE AND ADMINISTRATION:

As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations.

Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened. **Discard unused portion.**

CAUTIONS:

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

WARNINGS:

Additives may be incompatible. Consult with a veterinarian, if available. When introducing additives, use an aseptic technique. Mix thoroughly. **Do not administer** simultaneously with blood.

KEEP OUT OF REACH OF CHILDREN.

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.

Lot:

Exp.:

Mfg by: **Laboratorios Alfa S.R.L.**,
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10701, Dominican Republic.
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www.laboratoriosalfa.com
Made in Dominican Republic



NDC 72483-205-05

500 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

For Intravenous Infusion.

Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.

pH 3.2-6.5. **mEq/L:** 154 Sodium, 154 Chloride, **Osmolarity:** 586 mOsmol/L (calc).

INDICATIONS:

As a source of water, electrolytes and calories.

DOSAGE AND ADMINISTRATION:

As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations. Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened. **Discard unused portion.**

CAUTIONS:

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

Lot.:

Exp.:

FOR VETERINARY USE ONLY

Squeeze and inspect bottle before use, discard if leaks are found or if the solution contains solid particles. **Do not administer** unless solution is clear, and seal is intact.

WARNINGS:

Additives may be incompatible. Consult with a veterinarian, if available. When introducing additives, use an aseptic technique. Mix thoroughly. **Do not administer** simultaneously with blood.

KEEP OUT OF REACH OF CHILDREN.

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.

Mfg by: **Laboratorios Alfa S.R.L.**,
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Made in Dominican Republic



NDC 72483-205-10

1000 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE

INJECTION, USP

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

For Intravenous Infusion.

Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.

pH 3.2-6.5. **mEq/L:** 154 Sodium, 154 Chloride, **Osmolarity:** 586 mOsmol/L (calc).

INDICATIONS:

As a source of water, electrolytes and calories.

DOSAGE AND ADMINISTRATION:

As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations. Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened. **Discard unused portion.**

CAUTIONS:

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

Lot.:

Exp.:

FOR VETERINARY USE ONLY

Squeeze and inspect bottle before use, discard if leaks are found or if the solution contains solid particles. **Do not administer** unless solution is clear, and seal is intact.

WARNINGS:

Additives may be incompatible. Consult with a veterinarian, if available. When introducing additives, use an aseptic technique. Mix thoroughly. **Do not administer** simultaneously with blood.

KEEP OUT OF REACH OF CHILDREN.

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.

Mfg by: **Laboratorios Alfa S.R.L.**,
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10701, Dominican Republic.
Toll-Free: +1-800-969-0581 /
www.laboratoriosalfa.com
Made in Dominican Republic



Dextrose 5% in 0.9% sodium chloride (Bags)

Dextrose 5% in 0.9% Sodium Chloride Injection, USP

For Veterinary Use Only

Dextrose 5% in 0.9% Sodium Chloride 100 mL NDC 72483-205-08

Dextrose 5% in 0.9% Sodium Chloride 250 mL NDC 72483-205-07

Dextrose 5% in 0.9% Sodium Chloride 500 mL NDC 72483-205-06

Dextrose 5% in 0.9% Sodium Chloride 1000 mL NDC 72483-205-04

Dextrose 5% in 0.9% Sodium Chloride 3000 mL NDC 72483-205-03

Dextrose 5% in 0.9% Sodium Chloride 5000 mL NDC 72483-205-02



NDC 72483-205-08



100 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP
STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

FOR VETERINARY USE ONLY

For Intravenous Infusion.

Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.

pH 3.2-6.5. mEq/L: 154 Sodium, 154 Chloride, **Osmolarity:** 586 mOsmol/L (calc).

INDICATIONS: As a source of water, electrolytes and calories.

DOSAGE AND ADMINISTRATION: As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations. Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened.

Discard unused portion.

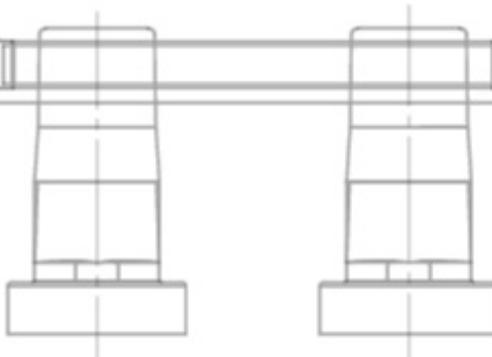
CAUTIONS: This is a single-dose container and does not contain preservatives. Squeeze and inspect bag before use, discard if leaks are found or if the solution contains solid particles. Do not administer unless solution is clear, and seal is intact.

WARNINGS: Additives may be incompatible. Consult with a veterinarian, if available. When introducing additives, use an aseptic technique. Mix thoroughly. Do not administer simultaneously with blood. **KEEP OUT OF REACH OF CHILDREN.**

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.

Mfg by: **Laboratorios Alfa S.R.L.**, Av. República de Colombia KM 13,
Santo Domingo Oeste, Santo Domingo 10701, Dominican Republic.
Toll-Free: +1-800-969-0581 / www.laboratoriosalfa.com
Made in Dominican Republic





50

NDC 72483-205-07



250 mL

250

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP
STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

FOR VETERINARY USE ONLY

For Intravenous Infusion.

Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.
pH 3.2-6.5, mEq/L: 154 Sodium, 154 Chloride, Osmolality: 586 mOsmol/L (calc).

INDICATIONS: As a source of water, electrolytes and calories.

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STORAGE: Store below 30°C (86°F).

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TAKE TIME - OBSERVE LABEL DIRECTIONS.



150

150

250

50

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Made in Dominican Republic



NDC 72483-205-06



500 mL

**5% DEXTROSE IN 0.9% SODIUM CHLORIDE
INJECTION, USP**

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

4

FOR VETERINARY USE ONLY

4

For Intravenous Infusion.

3

Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.

pH 3.2-6.5. **mEq/L:** 154 Sodium, 154 Chloride, **Osmolarity:** 586 mOsmol/L (calc).

3

INDICATIONS: As a source of water, electrolytes and calories.

DOSAGE AND ADMINISTRATION: As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations. Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened. **Discard unused portion.**

2

CAUTIONS: This is a single-dose container and does not contain preservatives. Squeeze and inspect bag before use, discard if leaks are found or if the solution contains solid particles. **Do not administer unless solution is clear, and seal is intact.**

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WARNINGS: Additives may be incompatible. Consult with a veterinarian, if available. When introducing additives, use an aseptic technique. Mix thoroughly. **Do not administer simultaneously with blood. KEEP OUT OF REACH OF CHILDREN.**

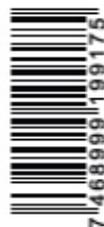
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STORAGE: Store at room temperature 25°C (77°F).

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

TAKE TIME - OBSERVE LABEL DIRECTIONS.

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KM 13, Santo Domingo Oeste, Santo Domingo 10701, Dominican
Republic. **Toll-Free: +1-800-969-0581 / www.laboratoriosalfa.com**
Made in Dominican Republic





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NDC 72483-205-04

1000 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

FOR VETERINARY USE ONLY

For Intravenous Infusion.

Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.
pH 3.2-6.5, mEq/L: 154 Sodium, 154 Chloride, Osmolality: 586 mOsmol/L (calc).

INDICATIONS: As a source of water and calories.

DOSAGE AND ADMINISTRATION: As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations. Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened. **Discard unused portion.**

CAUTIONS: This is a single-dose container and does not contain preservatives. Squeeze and inspect bag before use, discard if leaks are found or if the solution contains solid particles. **Do not administer unless solution is clear, and seal is intact.**

WARNINGS: Additives may be incompatible. Consult with a veterinarian, if available. When introducing additives, use an aseptic technique. Mix thoroughly. **Do not administer simultaneously with blood. KEEP OUT OF REACH OF CHILDREN.**

STORAGE: Store at room temperature 25°C (77°F).

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

TAKE TIME - OBSERVE LABEL DIRECTIONS.

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KM 13, Santo Domingo Oeste, Santo Domingo 10701, Dominican
Republic. Toll-Free: +1-800-969-0581 / www.laboratoriosalfa.com
Made in Dominican Republic



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102 MM

NDC 72483-205-03



3000 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

FOR VETERINARY USE ONLY

For Intravenous Infusion.

Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.

pH 3.2-6.5. mEq/L: 154 Sodium, 154 Chloride, **Osmolarity:** 586 mOsmol/L (calc).

INDICATIONS: As a source of water and calories.

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STORAGE: Store at room temperature 25°C (77°F).

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

TAKE TIME - OBSERVE LABEL DIRECTIONS.

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Made in Dominican Republic



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115 MM

NDC 72483-205-02  5000 mL

5% DEXTROSE IN 0.9% SODIUM CHLORIDE INJECTION, USP

STERILE, NONPYROGENIC AND PRESERVATIVE FREE SOLUTION

FOR VETERINARY USE ONLY

For Intravenous Infusion.
Each 100 mL contains: 0.9g sodium chloride, 5g Dextrose and water for injection, USP.
pH 3.2-6.5. **mEq/L:** 154 Sodium, 154 Chloride, **Osmolarity:** 586 mOsmol/L. (calc).

INDICATIONS: As a source of water and calories.

DOSAGE AND ADMINISTRATION: As directed by a veterinarian. Dosage is dependent upon age, weight, and clinical condition of the patient, as well as laboratory determinations. Administer intravenously using strict aseptic technique. Use the solution promptly following the initial entry. Use entire contents when first opened. **Discard unused portion.**

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TAKE TIME - OBSERVE LABEL DIRECTIONS.

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 Made in Dominican Republic


 7 4 6 8 9 0 1 1 9 9 2 0 6

115 MM

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: 8/2025

Laboratorios Alfa SRL