ALFA VETERINARY 0.9% SODIUM CHLORIDE- sodium chloride injection, solution 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 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 0.9% Sodium Chloride Injection, USP

Si-a	Compostion(mg/100 mL)			<u>Ionic Concentration</u> (mEq/L)	
Size (mL)	Sodium Chloride, <u>USP (NaCl)</u>	Osmolarity (mOsmol/L) <u>(Calculated)</u>	<u>pH</u>	<u>Sodium</u>	<u>Chloride</u>
100 250 500 1000	900	308	4.5-7.0	154	154

The Plastic container, a semi-rigid bottle, is made of a low density polyethylene 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.

OTHER SAFETY INFORMATION

CAUTION: Federal law (USA) restricts this drug to use by or on the order of a licensed veterinarian.

INDICATIONS AND USAGE

Veterinary 0.9% Sodium Chloride is indicated as a source of water and electrolytes.

Veterinary 0.9% Sodium Chloride injection, USP is also indicated for use as a priming solution in hemodialysis procedures.

CONTRAINDICATIONS

None known

WARNINGS

None known

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 veterinary 0.9% Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotrophin.

Do not administer unless solution is clear, and seal is intact.

DOSAGE & 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 NDC 72483-203-10 1000 mL in Plastic Bottle; NDC 72483-203-05 500 mL in Plastic Bottle; NDC 72483-203-25 250 mL in Plastic Bottle; NDC 72483-203-01 100 mL in Plastic Bottle

NDC 72483-203-10 1000 mL in Plastic Bottle

NDC 72483-203-05 500 mL in Plastic Bottle

NDC 72483-203-25 250 mL in Plastic Bottle

NDC 72483-203-01 100 mL in Plastic Bottle

Storage

DIRECTIONS FOR USE PLASTIC CONTAINER

Preparation and administration (Use Aspetic Technique):

- 1. Check for minute leaks by squeezing the container firmly. If leaks are found discard solutions as sterility may be impaired.
- 2. Suspend container from eyelet support.
- 3. Remove Plastic protector from port area at bottom of container.
- 4. Hold bottle in vertical position and insert IV administration set in outlet port.

To add Medication:

WARNING: Additives may be incompatible.

- 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.

Caution

Federal law (USA) restricts this drug to use by or on the order of a licensed veterinarian.

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, the solution containing dextrose may be contraindicated in patients with a known allergy to corn or corn products.

DIRECTIONS FOR USE PLASTIC CONTAINER

<u>Preparation and administration</u>

- 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. 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.

PACKAGE INSERT

For Animal Use Only

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

2.75"

NDC 72483-203-10

1000 mL

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. 900 mg Water for injection USP. 100 mL

Milliequivalentes per liter:

Sodium 154 mEq/L Chloride 154 mEq/L

Total osmolarity is 308 milliosmoles per

liter (calc). pH 4.5-7.0

INDICATIONS:

Veterinary 0.9% Sodium Chloride

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.

WARNING:

Additives may be incompatible. Consult

Injection, USP is indicated as a source of water and electrolytes.

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.

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.:







Manufactured by:

Laboratorios ALFA, S.R.L.

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

2.5"

NDC 72483-203-05

500 mL

0.9% SODIUM CHLORIDE INJECTION, USP VETERINARY USE

STERILE AND NONPYROGENIC SOLUTION

FOR ANIMAL USE ONLY

4.68

KEEP OUT OF REACH OF CHILDREN

COMPOSITION: Each 100 mL contains: Sodium Chloride, USP. 900 mg Water for injection USP. 100 mL

Milliequivalentes per liter:

Sodium 154 mEq/L Chloride 154 mEq/L

Total osmolarity is 308 milliosmoles per liter (calc). pH 4.5-7.0

INDICATIONS:

Veterinary 0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

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.

Lot.:

Exp.:

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.

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.



Manufactured by:

Laboratorios ALFA, S.R.L.

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

250 mL

NDC 72483-203-25

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. . 900 mg Water for injection USP. .100 mL

Milliequivalentes per liter:

Sodium 154 mEq/L Chloride 154 mEq/L Total osmolarity is 308 milliosmoles per liter (calc). pH 4.5-7.0

INDICATIONS:

Veterinary 0.9% Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

DOSAGE AND ADMINISTRATION:

As directed by a veterinarian.

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.

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).

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:

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

Lot.:

Exp.:





Manufactured by:



Santo Domingo
Dominican Republic
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1-809-544-0222



NDC 72483-203-01

100 mL

0.9% SODIUM CHLORIDE

VETERINARY USE

COMPOSITION:

Each 100 mL contains:

Sodium Chloride, USP. . 900 mg Water for injection USP. .100 mL

Milliequivalentes per liter:

Sodium 154 mEq/L Chloride 154 mEq/L Total osmolarity is 308 millios moles per liter (calc). pH 4.5-7.0

INDICATIONS:

Veterinary 0.9% Sodium Chloride Injection, USP is indicated

as a source of water and electrolytes.

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.

Lote:

Exp.:

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.

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.





OBSERVE LABEL DIRECTIONS







Laboratorios ALFA, S.R.L.

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

ALFA VETERINARY 0.9% SODIUM CHLORIDE

sodium chloride injection, solution injection, solution

Product Information

Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:72483-203

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32Z N48698)	SODIUM CHLORIDE	900 mg in 100 mL		

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:72483-203-10	1000 mL in 1 BOTTLE, PLASTIC				
2	NDC:72483-203-05	500 mL in 1 BOTTLE, PLASTIC				
3	NDC:72483-203-25	250 mL in 1 BOTTLE, PLASTIC				
4	NDC:72483-203-01	100 mL in 1 BOTTLE, PLASTIC				

Marketing Information				
Marketing Category	Marketing Start Date	Marketing End Date		
unapproved drug other		12/04/2019		
otriei				

Labeler - Laboratorios Alfa SRL (815941244)

Revised: 2/2024 Laboratorios Alfa SRL