SODIUM BICARBONATE- sodium bicarbonate injection
Phoenix

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.

Phoenix
Sodium Bicarbonate 8.4%

INDICATIONS:

For treatment of metabolic acidosis. See package insert for specific indications.

Each mL contains:

Sodium Bicarbonate.....84 mg

(equal to 1 mEq/mL)

Water for Injection.....q.s.

Dosage and Administration:

Administer intravenously. See package insert for complete directions for use and dosage information.

RMS 92-307

L814-100312

Lot No.

Exp. Date

Phoenix™

Manufactured for:

Clipper Distributing Company, LLC.

St. Joseph, MO 64507

Trademarks are the property of

Clipper Distributing Company, LLC

Take Time Observe Label Directions

Manufactured by:

Nova-Tech, Inc. Grand Island, NE 68801

for Neogen Corporation.

Store at temperatures between 15°and 30°C (59°-86°F).

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

Warning:

This is a sterile single dose vial. No preservatives have been added. Discard unused portion after use. Do not use if solution is hazy, cloudy, or contains a precipitate. The total osmolar concentration of this package is approximately 2000 mOsm/L.

Package Insert

SODIUM BICARBONATE 8.4%

STERILE NONPYROGENIC SOLUTION

FOR VETERINARY USE ONLY

DESCRIPTION: Sodium Bicarbonate 8.4% is a sterile nonpyrogenic preparation of sodium bicarbonate ($NaHCO_3$) in Water for Injection. Each 100 mL contains 8.4 grams of sodium bicarbonate (100 mEq/100 mL each of sodium and bicarbonate). This concentrated solution has an approximate pH of 7.8.

ACTIONS: Sodium Bicarbonate is useful in the treatment of metabolic acidosis due to a wide variety of causes. Sodium Bicarbonate therapy increases plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses the clinical manifestations of acidosis. Sodium Bicarbonate also alkalinizes the urine.

INDICATIONS: Sodium Bicarbonate is indicated in the treatment of metabolic acidosis which may be due to severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, cardiac arrest and severe primary lactic acidosis. Sodium Bicarbonate is also indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate. Sodium Bicarbonate 8.4% is indicated in the treatment of metabolic acidosis in cattle, horses, sheep, swine and dogs depending upon causative factor.

CONTRAINDICATIONS: Sodium Bicarbonate is contraindicated in animals losing chloride by vomiting and in animals receiving diuretics known to produce a hypochloremic alkalosis.

PRECAUTIONS: Bicarbonate therapy is directed at producing a substantial correction of low total CO_2 content and blood pH, but risks of overdosage and alkalosis should be avoided. Repeated fractional doses and periodic monitoring by appropriate laboratory tests are therefore recommended to minimize the possibility of overdosage. Sodium Bicarbonate addition to parenteral solutions containing calcium should be avoided except where compatibility has been previously established. Precipitation or haze may result from

sodium bicarbonate-calcium admixtures, and the resulting solution should not be administered.

DOSAGE AND ADMINISTRATION: Sodium Bicarbonate 8.4% is injected intravenously. Caution should be taken in emergencies where very rapid infusion of large quantities of bicarbonate is indicated, such as cardiac arrest. Sodium Bicarbonate solutions are hypertonic and may produce an undesirable rise in plasma sodium concentration during the process of correction of metabolic acidosis. During cardiac arrest, however, the risks from acidosis exceed those of hypernatremia. In cattle and horses, 200 to 300 mL of 8.4% solution may be given undiluted by rapid infusion using a needle and syringe.

Sodium Bicarbonate 8.4% solution is often added to other intravenous fluids for the less urgent forms of metabolic acidosis. The amount of bicarbonate to be given over a 4 to 8 hour period is approximately 2 to 5 mEq per kg of body weight (1-2.5 mL/lb body weight) depending upon the severity of the acidosis as judged by the lowering of total CO_2 content, blood pH and clinical condition of the animal.

Bicarbonate therapy should always be planned in stepwise fashion since the degree of response from a given dose is not precisely predictable. Initially, an infusion of 2 to 5 mEq per kg of body weight over a period of 4 to 8 hours will produce a measurable improvement in the abnormal acid-base status of the blood. Completion of therapy is dependent upon the clinical response of the animal. If severe symptoms have abated, then frequency of administration and size of the dose should be reduced.

OVERDOSAGES: In case alkalosis occurs, the bicarbonate should be stopped and the animal managed according to the degree of alkalosis present. Sodium chloride injection (0.9%) may be given intravenously; potassium chloride also may be indicated if there is hypokalemia. Severe alkalosis may be accompanied by hyperirritability or tetany, and these symptoms may be controlled by calcium gluconate. An acidifying agent such as ammonium chloride may also be indicated in severe alkalosis.

HOW SUPPLIED: Sodium Bicarbonate 8.4% is supplied in a 100 mL single dose vial.

WARNING: This is a sterile single dose vial. No preservatives have been added. Discard unused portion after use. Do not use if solution is hazy, cloudy or contains a precipitate.

Store at a temperature between 15°-30° C (59°-86° F).

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

RMS# 92-516 NTI# 18-9078

Neogen

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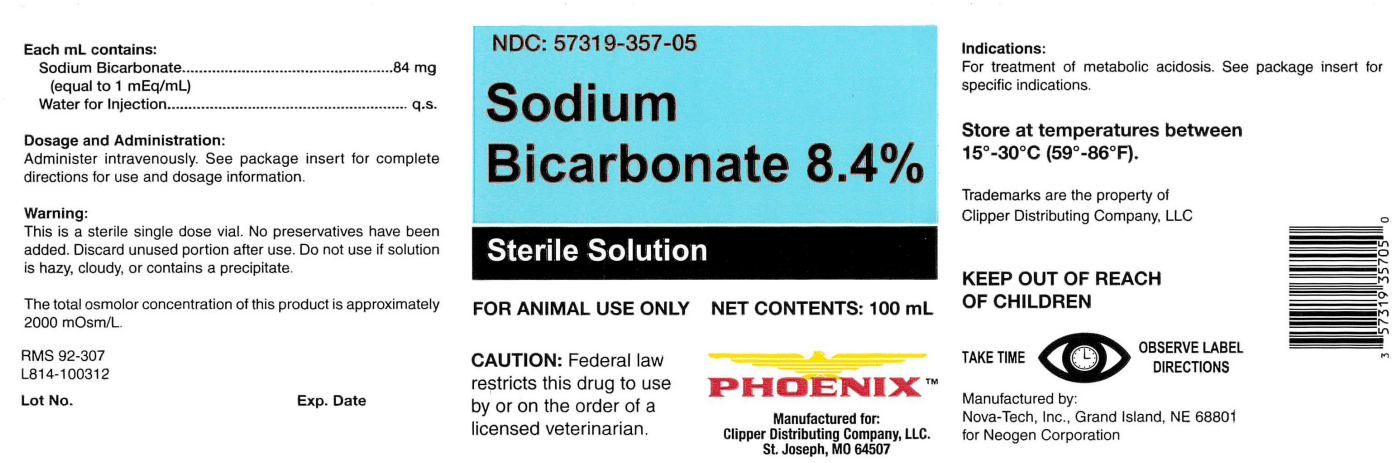
L1556-0316

Sodium Bicarbonate



SODIUM BICARBONATE

sodium bicarbonate injection

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:57319-357
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	84 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57319-357-05	100 mL in 1 VIAL, SINGLE-USE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/20/2011	

Labeler - Phoenix (150711039)

Registrant - Nova-Tech, Inc (196078976)

Establishment

Name	Address	ID/FEI	Business Operations
Nova-Tech, Inc		196078976	manufacture

Revised: 11/2019 Phoenix