HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SODIUM BICARBONATE INJECTION safely and effectively. See full prescribing information for SODIUM BICARBONATE INJECTION.

SODIUM BICARBONATE injection, for intravenous use
Initial U.S. Approval: 1986

---------- INDICATIONS AND USAGE----------

Sodium bicarbonate injection is an alkalinizing agent indicated:

- to raise plasma pH in adults and pediatric patients with clinically significant metabolic acidosis. (1.1)
- to alkalinize the urine in drug poisoning in adult and pediatric patients in cases in which urinary drug elimination is enhanced by urinary alkalinaztion. (1.2)

Limitation of Use

Do not use sodium bicarbonate injection in settings where rapid administration of sodium bicarbonate is required, such as cardiac arrest. In such situations use a more concentrated solution.

----------DOSAGE AND ADMINISTRATION----------

Sodium bicarbonate injection is administered by intravenous infusion. (2.1)
Do NOT dilute prior to administration. (2.1)

Recommended Dosage in Adults and Pediatric Patients 2 Years of Age and Older

Administer 2 mEq/kg to 5 mEq/kg of sodium bicarbonate injection over a four- to eight-hour period, depending upon the severity of metabolic acidosis as assessed by serum bicarbonate concentration, total CO_2, blood pH and the clinical condition of the patient. (2.2)

Recommended Dosage in Pediatric Patients Less Than 2 Years of Age, including Neonates

Administer 1 mEq/kg to 2 mEq/kg of sodium bicarbonate injection over a four- to eight-hour period. Avoid rapid or bolus administration. (2.2)

---------- DOSAGE FORMS AND STRENGTHS----------

Sodium bicarbonate injection USP, 150 mEq/1,000 mL (0.15 mEq/mL) in a single-dose infusion bag. (3)

---------- CONTRAINDICATIONS ----------

Sodium bicarbonate injection is contraindicated in patients who are losing chloride by vomiting or from continuous gastrointestinal suction and in patients receiving diuretics known to produce a hypochloremic alkalosis.

---------- WARNINGS AND PRECAUTIONS----------

- Edema with Sodium Retention: Monitor patients who are sensitive to sodium intake (heart failure, hypertension, kidney disease, anuria, edema) for signs of fluid overload and adjust as appropriate. (5.1)
- Electrolyte Imbalances: Therapy with sodium bicarbonate injection can result in metabolic alkalosis (associated with muscular twitchings, irritability and tetany) and hypernatremia. Monitor electrolytes periodically during administration and treat abnormalities appropriately. Dosing with sodium bicarbonate injection results in a large volume of administration in younger and lighter weight pediatric patients. Consider use of more concentrated sodium bicarbonate formulations in these pediatric populations. (5.2)
- Extravasation: Prompt elevation of the area, warmth, and local injection of lidocaine or hyaluronidase are recommended to reduce the likelihood of tissue sloughing at the site. (5.3)

---------- ADVERSE REACTIONS----------

Adverse reactions include edema with sodium retention, electrolyte imbalances and extravasation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals LLC at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- USE IN SPECIFIC POPULATIONS ----------

- Pediatric Use: Rapid injection may result in complications of central nervous system related to electrolyte imbalances in pediatric patients less than two years of age. (8.4)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 7/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Treatment of Clinically Significant Metabolic Acidosis

Sodium bicarbonate injection is indicated to raise plasma pH in adults and pediatric patients with clinically significant metabolic acidosis.

1.2 Urinary Alkalization in Drug Poisoning

Sodium bicarbonate injection is indicated to alkalinize the urine in drug poisoning in adult and pediatric patients in cases in which urinary drug elimination is enhanced by urinary alkalinaztion.

Limitation of Use
Do not use sodium bicarbonate injection in settings where rapid administration of sodium bicarbonate is required, such as cardiac arrest. In such situations use a more concentrated solution.

2 DOSAGE AND ADMINISTRATION

2.1 General Administration Instructions

Inspect parenteral drug products for particulate matter and discoloration prior to administration. Do not use if the solution is colored or cloudy or if it contains particulate matter. Discard any unused portion.

Sodium bicarbonate injection is a ready to administer product that requires no further dilution prior to infusion. Administer sodium bicarbonate injection by intravenous infusion, via a dedicated line.

Individualize dosage depending on the severity of the acidosis.

Treatment of metabolic acidosis with sodium bicarbonate should be superimposed on measures designed to address the underlying cause of metabolic acidosis.

2.2 Recommended Dosage

Recommended Dosage in Adults and Pediatric Patients 2 Years of Age and Older
Administer 2 mEq/kg to 5 mEq/kg of sodium bicarbonate injection over a four- to eight-hour period, depending upon the severity of metabolic acidosis as assessed by serum bicarbonate concentration, total CO_2, blood pH and the clinical condition of the patient.

Recommended Dosage in Pediatric Patients Less Than 2 Years of Age, including Neonates
Administer 1 mEq/kg to 2 mEq/kg of sodium bicarbonate injection over a four- to eight-hour period. Avoid rapid or bolus administration *[see Warnings and Precautions (5.2), Use in Specific Populations (8.4)]*.

3 DOSAGE FORMS AND STRENGTHS

Sodium bicarbonate injection, USP is a sterile, nonpyrogenic, clear, colorless solution available as:
Injection: 150 mEq/1,000 mL (0.15 mEq/mL) in a ready-to-use single-dose infusion bag.

4 CONTRAINDICATIONS

Sodium bicarbonate injection is contraindicated in patients who are losing chloride by vomiting or from continuous gastrointestinal suction and in patients receiving diuretics known to produce a hypochloremic alkalosis.

5 WARNINGS AND PRECAUTIONS

5.1 Edema with Sodium Retention

Sodium bicarbonate injection can cause sodium retention and volume overload. Monitor patients who are sensitive to sodium intake (heart failure, hypertension, kidney disease, anuria, edema) for signs of fluid overload and adjust sources of sodium as appropriate.

5.2 Electrolyte Imbalances

Sodium bicarbonate injection may cause electrolyte imbalances. Overly aggressive therapy with sodium bicarbonate injection can result in metabolic alkalosis (associated with muscular twitchings, irritability and tetany) and hypernatremia. Monitor electrolytes periodically during administration and treat abnormalities appropriately.

Dosing with sodium bicarbonate injection results in a large volume of administration in younger and lighter weight pediatric patients. Consider use of more concentrated sodium bicarbonate formulations in these pediatric populations *[see Dosing and Administration (2)]*.

5.3 Extravasation

Inadvertent extravasation of intravenously administered hypertonic solutions of sodium bicarbonate have been reported to cause chemical cellulitis because of their alkalinity, with tissue necrosis, ulceration or sloughing at the site of infiltration. Prompt elevation of the area, warmth, and local injection of lidocaine or hyaluronidase are recommended to reduce the likelihood of tissue sloughing at the site of intravenous solution extravasation.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in labeling:

- Edema with Sodium Retention *[see Warnings and Precautions (5.1)]*
- Electrolyte Imbalances *[see Warnings and Precautions (5.2)]*
- Extravasation *[see Warnings and Precautions (5.3)]*

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from published literature over decades of use have not identified a drug associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Physiological replacement of sodium bicarbonate is not expected to lead to increased risk of adverse fetal or maternal outcomes. Animal reproduction studies have not been conducted with sodium bicarbonate.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

There are no data on the presence of sodium bicarbonate in either human or animal milk, the effects on the breast-fed infant or the effects on milk production following administration of sodium bicarbonate injection.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for sodium bicarbonate and any potential adverse effects on the breast-fed child from sodium bicarbonate or from the underlying maternal condition.

8.4 Pediatric Use

Sodium bicarbonate injection is indicated in pediatric patients:

- To raise plasma pH in pediatric patients with clinically significant metabolic acidosis
- To alkalinize the urine in drug poisoning in cases in which urinary drug elimination is enhanced by urinary alkalinization

Rapid injection of sodium bicarbonate injection may result in complications of the central nervous system related to electrolyte imbalances in pediatric patients less than two years of age *[see Dosing and Administration (2)* and *Warnings and Precautions (5.2)].*

8.5 Geriatric Use

Clinical studies of sodium bicarbonate injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

10 OVERDOSAGE

If alkalosis results, discontinue the sodium bicarbonate injection and manage the patient according to the degree of alkalosis present. Administer potassium chloride if hypokalemia is present. Treat severe alkalosis accompanied by hyperirritability or tetany with calcium gluconate. In severe alkalosis, consider use of acidifying agent such as ammonium chloride *[see Warnings and Precautions (5.2)].*

11 DESCRIPTION

Sodium bicarbonate injection, USP is an alkalinizing agent, supplied as a sterile, nonpyrogenic, clear, colorless, ready-to-use solution of sodium bicarbonate ($NaHCO_3$) in water for injection for administration by the intravenous infusion as an electrolyte replenisher and systemic alkalizer.

Sodium bicarbonate, 12.6 mg is equal to 0.15 milliequivalent each of Na^+ and HCO_3^-.
Sodium bicarbonate, USP is chemically designated $NaHCO_3$, molecular weight 84.01 g/mol, a white crystalline powder soluble in water and insoluble in ethanol.

Solution is offered in concentration of 1.26% *[see How Supplied Storage and Handling (16.1)]*.

The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as an intravenous infusion. Carbon dioxide is added to adjust pH between 7 to 8.5. When smaller doses are required, the unused portion should be discarded.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Intravenous sodium bicarbonate therapy increases plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH.

12.2 Pharmacodynamics

Intravenous sodium bicarbonate therapy increases plasma bicarbonate, buffers excess hydrogen ion concentration, and raises blood pH.

12.3 Pharmacokinetics

Distribution
Sodium bicarbonate in water dissociates to provide sodium (Na^+) and bicarbonate (HCO_3^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid. Bicarbonate (HCO_3^-) is a normal constituent of body fluids.

Elimination
Plasma bicarbonate concentration is regulated by the kidney through acidification of the urine when there is a deficit or by alkalinization of the urine when there is an excess. Bicarbonate anion is considered "labile" since at a proper concentration of hydrogen ion (H^+) it may be converted to carbonic acid (H_2CO_3) and then to its volatile form, carbon dioxide (CO_2) excreted by the lung.

In a healthy adult with normal kidney function, practically all the glomerular filtered bicarbonate ion is reabsorbed; less than 1% is excreted in the urine.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis, mutagenesis and impairment of fertility studies have not been conducted with sodium bicarbonate.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Sodium bicarbonate injection USP, 150 mEq/1,000 mL (0.15 mEq/mL) is supplied as a sterile, nonpyrogenic, clear, colorless solution available in a ready-to-use infusion bag in the following dosage form:

Unit of Sale	Unit of Use	Conc %	mg/mL ($NaHCO_3$)	mEq/mL (Na^+)	mEq/mL (HCO_3^-)	mEq/Container size (mL)	mOsmol
NDC 80830-2613-2 Carton containing 6 Pouch	NDC 80830-2613-1 1,000 mL Single-dose Infusion Bag in a Pouch	1.26	12.6	0.15	0.15	150/1,000	0.3/mL

16.2 Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Avoid excessive heat. Protect from freezing. Keep covered in the pouch until time of use.

Each ready-to-use infusion bag contains no preservatives. Once the ready-to-use infusion bag has been removed from the pouch, the ready-to-use infusion bag should be used within 24 hours, with any unused portion discarded.

17 PATIENT COUNSELING INFORMATION

Advise patients to report signs and symptoms suggestive of fluid and/or solute overloading, electrolyte imbalances, overhydration, congested states or pulmonary edema *[see Warnings and Precautions (5.1)]*.

Advise the patient, family or caregiver to report signs of extravasation *[see Warnings and Precautions (5.3)]*.

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