PRESCRIBING INFORMATION

Sodium Bicarbonate Injection, USP

84 mg / mL (8.4%)

Sterile solution

ALKALIZER

FOR CORRECTION OF METABOLIC ACIDOSIS AND OTHER CONDITIONS REQUIRING SYSTEMIC ALKALINIZATION

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ACTION AND CLINICAL PHARMACOLOGY

Intravenous sodium bicarbonate therapy increases plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses the clinical manifestations of acidosis.

Sodium bicarbonate in water dissociates to provide sodium (Na^+) and bicarbonate (HCO_3^-) ions. Sodium (Na^+) is the principal cation of extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Bicarbonate (HCO_3^-) is a normal constituent of body fluids and the normal plasma level ranges from 24 to 31 mmol (mEq) / liter. Plasma 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 thence to its volatile form, carbon dioxide (CO_2) excreted by the lung. Normally a ratio of 1:20 (carbonic acid: bicarbonate) is present in the extracellular fluid. 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.

INDICATIONS AND CLINICAL USE

Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is further indicated in the treatment of certain drug intoxications, including barbiturates (where dissociation of the barbiturate-protein complex is desired), in poisoning by salicylates or methyl alcohol and in hemolytic reactions requiring alkalinization of the urine to diminish nephrotoxicity of blood pigments. Sodium bicarbonate is also indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate.

Treatment of metabolic acidosis should, if possible, be superimposed on measures designed to control the basic cause of the acidosis - e.g., insulin in uncomplicated diabetes, blood volume restoration in shock. But since an appreciable time interval may elapse before all of the ancillary effects are brought about, bicarbonate therapy is indicated to minimize risks inherent to the acidosis itself.

Vigorous bicarbonate therapy is required in any form of metabolic acidosis where a rapid increase in plasma total CO_2 content is crucial - e.g., cardiac arrest, circulatory insufficiency due to shock or severe dehydration, and in severe primary lactic acidosis or severe diabetic acidosis.

CONTRAINDICATIONS

Sodium Bicarbonate Injection, USP 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

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 exists edema with sodium retention.

In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention.

The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

Additives may be incompatible. Consult with pharmacist if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Extravascular infiltration should be avoided (see ADVERSE REACTIONS).

PRECAUTIONS

The aim of all bicarbonate therapy is to produce a substantial correction of the low total CO_2 content and blood pH, but the risks of overdosage and alkalosis should be avoided. Hence, repeated fractional doses and periodic monitoring by appropriate laboratory tests are recommended to minimize the possibility of overdosage.

The potentially large loads of sodium given with bicarbonate require that caution be exercised in the use of sodium bicarbonate in patients with congestive heart failure or other edematous or sodium-retaining states, as well as in patients with oliguria or anuria. See AVAILABILITY OF DOSAGE FORMS for amounts of sodium present in solutions.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

Potassium depletion may predispose to metabolic alkalosis and coexistent hypocalcemia may be associated with carpopedal spasm as the plasma pH rises. These dangers can be minimized if such electrolyte imbalances are appropriately treated prior to or concomitantly with bicarbonate infusion.

Rapid injection (10 mL / min) of hypertonic Sodium Bicarbonate Injection, USP solutions into neonates and children under two years of age may produce hypernatremia, a decrease in cere-brospinal fluid pressure and possible intracranial hemorrhage. The rate of administration in such patients should therefore be limited to no more than 8 mmol (mEq) / kg / day. A 4.2% solution may be preferred for such slow administration.
In emergencies such as cardiac arrest, the risk of rapid infusion must be weighed against the potential for fatality due to acidosis.

The addition of sodium bicarbonate 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.

Pregnancy

Animal reproduction studies have not been conducted with sodium bicarbonate. It is also not known whether sodium bicarbonate can cause fetal harm when administered to a pregnant woman. Sodium bicarbonate should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Overly aggressive therapy with Sodium Bicarbonate Injection, USP can result in metabolic alkalosis (associated with muscular twitchings, irritability, and tetany) and hypernatremia.

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 part, warmth and local injection of lidocaine or hyaluronidase are recommended to prevent sloughing of extravasated intravenous infusions.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Should alkalosis result, the bicarbonate should be stopped and the patient managed according to the degree of alkalosis present. A 0.9% sodium chloride intravenous injection may be given; potassium chloride may also

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 (see WARNINGS and PRECAUTIONS).

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

DOSAGE AND ADMINISTRATION

Sodium Bicarbonate Injection, USP is administered by the intravenous route.

In cardiac arrest, a rapid intravenous dose of 200 to 300 mmol (mEq) of bicarbonate, given as a 8.4% solution, is suggested for adults. Caution should be observed in emergencies where very rapid infusion of large quantities of bicarbonate is indicated. Bicarbonate solutions are hypertonic and may produce an undesirable rise in plasma sodium concentration in the process of correcting the metabolic acidosis. In cardiac arrest, however, the risks from acidosis exceed those of hypernatremia.

In infants (up to two years of age), intravenous administration at a dose not to exceed 8 mmol (mEq) / kg / day is recommended. Slow administration rates are recommended in neonates, to guard against the possibility of producing hypernatremia, decreasing cerebrospinal fluid pressure and inducing intracranial hemorrhage.

The table below shows the volume of Sodium Bicarbonate Injection, USP and number of vials needed to achieve the recommended maximum daily dose of 8 mmol (mEq)/kg/day in neonates, based on normal and average birth weights:

Body Weight (kg)	**Total Dose to Achieve 8 mmol/kg/day**	**Volume of Sodium Bicarbonate Injection**	**Number of Vials Needed**
2.5	20 mmol	20 mL	0.40 x 50 mL vials
3.3	26.4 mmol	~ 26 mL	0.53 x 50 mL vials
4.5	36 mmol	36 mL	0.72 x 50 mL vials

In less urgent forms of metabolic acidosis, Sodium Bicarbonate Injection, USP may be added to other intravenous fluids. The amount of bicarbonate to be given to older children over a four to eight hour period is approximately 2 to 5 mmol (mEq) / kg of 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 patient. Bicarbonate therapy should always be planned in a stepwise fashion since the degree of response from a given dose is not precisely predictable. Initially an infusion of 2 to 5 mmol (mEq) / kg body weight over a period of 4 to 8 hours will produce a measurable improvement in the abnormal acid base status of the blood. The next step of therapy is dependent upon the clinical response of the patient. If severe symptoms have abated, then the frequency of administration and the size of the dose may be reduced.

In general, it is unwise to attempt full correction of a low total CO_2 content during the first 24 hours of therapy, since this may be accompanied by an unrecognized alkalosis because of a delay in the readjustment of ventilation to normal. Owing to this lag, the achievement of total CO_2 content of about 20 mmol (mEq) / liter at the end of the first day of therapy will usually be associated with a normal blood pH. Further

modification of the acidosis to completely normal values usually occurs in the presence of normal kidney function when and if the cause of the acidosis can be controlled. Values for total CO_2, which are brought to normal or above normal within the first day of therapy, are very likely to be associated with grossly alkaline values for blood pH, with ensuing undesired side effects.

DESCRIPTION

Sodium Bicarbonate Injection, USP is a sterile nonpyrogenic, hypertonic solution of sodium bicarbonate in Water for Injection USP.

The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single dose injection. When smaller doses are required, the unused portion should be discarded.

Stability and Storage Recommendations

Store between 15 °C and 30 °C. Protect from freezing and avoid excessive heat.

Note: brief exposure up to 40 ºC does not adversely affect the product.

AVAILABILITY OF DOSAGE FORMS

Sodium Bicarbonate Injection, USP is supplied in single-dose vials and packed in trays of 25 in the following format:

Sodium Bicarbonate Injection, USP 8.4% is packaged in a 50 mL Type I glass vial with a stopper that is not made with natural rubber latex and an aluminium seal.

Vial Size	**Conc. (%)**	**mg / mL ($NaHCO_3$)**	**mmol (mEq) / mL (Na^+)**	**mmol (mEq) / mL (HCO_3^-)**	**mmol (mEq) / Container size (mL)**	**mOsm / mL**	**pH**
50 mL	8.4	84	1	1	50 / 50	2	7.0 to 8.5

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration,
whenever solution and container permit.

Do not use unless the solution is clear and container or seal intact. Discard if contains a precipitate.

If you want more information about Sodium Bicarbonate Injection, USP

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website https://www.fresenius-kabi.com/en-ca/, or by calling 1-877-821-7724.

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