7.5% SODIUM BICARBONATE

Injection, USP
44.6 mEq (0.9 mEq/mL) Rx only


1.79 mOsmol/mL (calc) pH 8.0 (7.0 to 8.5)

Hospira, Inc., Lake Forest, IL 60045, USA
8.4% Sodium Bicarbonate

Injection, USP
50 mEq (1 mEq/mL) Rx only

Discard unused portion.
2 mOsmol/mL (calc.) pH 8.0 (7.0 to 8.5).

Hospira, Inc., Lake Forest, IL 60045, USA
8.4% SODIUM BICARBONATE Injection, USP
50 mEq (1 mEq/mL)

OP EN

50 mL
NDC 0409-3495-16

8.4% SODIUM BICARBONATE Inj., USP
50 mEq (1 mEq/mL)

OP EN

PRESS AND PULL TO OPEN

USE ASEPTIC TECHNIQUE

1. Assemble plunger to syringe.
2. Remove luer cover.
3. Hold plunger and push barrel forward to relieve any resistance that may be present.
4. Pull the barrel down until air is expelled from the syringe.

Ansysr® II
with male luer lock adapter

Unit of Use Syringe
Rx only

50 mL
NDC 0409-3495-16

8.4% SODIUM BICARBONATE Inj., USP
50 mEq (1 mEq/mL)

OP EN

PRESS AND PULL TO OPEN

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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 is markedly less effective in providing sodium (Na+) and bicarbonate (HCO3-) ions. Sodium (Na+) is the principal cation of the extracellular fluid and plays a large part in the physiology of fluid and electrolyte disturbances. Bicarbonate (HCO3-) is a normal constituent of the intracellular fluid and the normal plasma levels range from 24 to 34 mEq/L. Plasma concentration is regulated by the kidney through acidification of the urine or by retention in the urine when there is an excess. Bicarbonate anion is considered "stable" only at a proper concentration of hydrogen ions (H+), it may be converted to carbonic acid (H2CO3) and thence to its volatile form, carbon dioxide, or be reconverted to bicarbonate. The "bicarbonate buffer" is present in the extracellular fluid. In a healthy adult with normal ventilatory function and a normal pHi, the glomerular filtrate bicarbonate ion is reabsorbed; less than 1% is carried in the urine.

INDICATIONS AND USAGE

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, extrapulmonary circulations of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is further indicated in the treatment of certain drug administrations including barbiturates before dissection of the barbiturate protein complex is desired, in poisoning by sympathomimetic and methylnitric reactions requiring alkalization of the urine to decrease methemoglobinemia and its breakdown products. Sodium bicarbonate also is indicated in severe burns which is often accompanied by a significant base deficit.

OVERDOSAGE

Should alkalosis result, the bicarbonate should be stopped and the patient managed accordingly to the degree of alkalosis present. 5% sodium citrate introduction may be given; potassium bicarbonate introduction may also be given if indicated. Hyperkalemia may be accompanied by heart block or tachyarrhythmias which may be controlled by calcium gluconate. An additional mechanism for extracorporeal elimination of potassium may be considered in severe alkalosis. See WARNINGS and PRECAUTIONS.

DOSEAGE AND ADMINISTRATION

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

In cardiac arrest, a rapid intravenous dose of one to two 50 ml syringes (44 to 88 mEq) should be given initially and continued at a rate of 15 to 30 ml/min. 10 to 50 mEq may be given in 10 minutes if necessary (as indicated by arterial pH and blood gas monitoring) to reverse the acidosis. Calcium gluconate is recommended in emergencies where very rapid effects are required. Sodium bicarbonate is indicated when the bicarbonate concentration is known to be low and may produce a more rapid alkalization in moderate acidosis. Sodium bicarbonate should not be used in the treatment of severe acidosis without correction of the metabolic acidosis. In cardiac arrest, however, the heart rate may exceed the respiratory rate.

In less urgent forms of metabolic acidosis, Sodium Bicarbonate Injection, USP should not be given in other intravenous fluids. The amount of bicarbonate to be given to older children and adults over a three to eight hour period is approximately 1 to 5 mEq/kg body weight depending upon the severity of the acidosis as judged by the lowering of total CO2 content, blood pH and clinical condition of the patient. Metabolic acidosis associated with shock, therapy should be monitored by measuring blood gases, plasma electrolytes, arterial blood lactate, hematocrit and cardiac rhythm. Bicarbonate therapy should always be planned in a recovery phase since the degree of response from a given dose is not precisely predictable. Initially an infusion of 2 to 5 mEq/kg body weight over a period of 1 to 2 hours will produce a measurable improvement in the arterial acid-base status of the blood. The next step of therapy is dependent upon the clinical response of the patient. If symptoms of hyperventilation develop, 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 CO2 content during the first 24 hours of therapy, since this may be accompanied by an unregulated alkalosis because of a delay in the readjustment of ventilation to normocarbia. During this time, the achievement of total CO2 content of about 30 mEq/L at the end of the first day of therapy will usually be associated with a normal blood pH. Lower values of total CO2 content may produce respiratory alkalosis and thus may be undesirable or may be associated with diminished cardiac output. It is possible that the CO2 content of the arterial blood may be increased to such a degree that cardiovascular collapse may occur. It may be necessary to use a more prolonged period of time for full correction during the first day. The usual practice is to use a period of 12 to 24 hours during the initial period of therapy to correct the acidosis. Some authorities recommend a total dose of 10 to 20 mEq/kg for the initial treatment, but there is no consistent evidence that a more rapid correction is desirable.

The potential large loads of sodium given with bicarbonate require that caution be used in the use of sodium bicarbonate in patients with congestive heart failure or other edematous sodium or sodium retaining states, as well as in patients receiving diuretics or corticosteroids. Sodium retention and water retention may occur with the administration of sodium bicarbonate. The risk of sodium and fluid overload must be balanced against the potential for fatal outcome due to acidosis.

CONTRAINDICATIONS

Sodium Bicarbonate Injection, USP is contraindicated in patients who are losing chloride by vomiting or from chronic gastrointestinal suction, and in patients receiving diuretics known to produce a hyperchloremic alkalosis.

WARNINGS

Solutions containing sodium ions should be used with great care, especially in patients with congestive heart failure, severe renal insufficiency and in clinical situations in which there exists sodium retention.

In patients with diminished renal function, administration of solutions containing sodium may result in sodium retention. The intravenous administration of these solutions can cause fluid retention; edema and/or fluid overload in patients with advanced cardiac disease, ascites, edematous states or pulmonary edema. Extravascular infusions should be avoided, use ADVERSE REACTIONS.

PRECAUTIONS

Do not use unless solution is clear and the container or seal is intact. Discard unused portion.

Adverse drug reactions are unusual. Cardiac arrest has been reported in association with sodium bicarbonate injection. Use of sodium bicarbonate in children is not recommended.

SODIUM BICARBONATE INJECTION, USP

SODIUM BICARBONATE INJECTION, USP is supplied in the following dosage forms:

- 300 mL ampules
- 1000 mL ampules

Sodium Bicarbonate Injection, USP is a sterile, nonpyrogenic, hypertonic solution of sodium bicarbonate (NaHCO3) in water for injection for administration by the intravenous route as an electrolyte replenisher and systemic alkalizer.

Solutions are available in concentrations of 1.0% and 8.4%. See Table in New SUPPLIED section for contents and characteristics.

The solutions in the Ampul® are available in concentrations of 0.8% (0.8 to 0.8) and 8.4%. The solutions in the New SUPPLIED section for contents and characteristics.

The solutions in the Ampul® have an osmolarity of 8.0 (0.8 to 0.8) and 8.4. The solutions contain no bacteriostatic, antimicrobial agent or added buffer and are intended only for use as a single-use dose. When another dose is required, the unused portion should be discarded with the ampul and unit dose vial.

Sodium bicarbonate, 84 mg is equivalent to one milliequivalent of sodium bicarbonate and USP. Sodium bicarbonate, USP is chemically designated NaHCO3, a white crystalline powder soluble in water. Water for Injection, USP is chemically designated H2O.

The solution is made from a specially formulated polypropylene. Water-penetrates from inside the container at an extremely slow rate which will have an insignificant effect on solution concentration over the expected shelf life. Solutions in contact with the plastic container may become slightly cloudy and brownish in color due to the small amount of water.

Ampul® III for Unit Dose Syringes

5/2000 Hospira, Inc. Lake Forest, IL 60045 USA

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