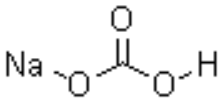
BIO-SODA®

Each tablet contains
Sodium bicarbonate 500 mg

DESCRIPTION:



Molecular Formula: $NaHCO_3$
Chemical names: Sodium Bicarbonate, Sodium Hydrogen Carbonate
Sodium bicarbonate is an Alkalinizing Agent; Antacid; Electrolyte Supplement, Oral; Electrolyte Supplement

PHARMACOLOGY:
Pharmacodynamics
Sodium bicarbonate is a systemic alkalizing agent which increases plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses the clinical manifestations of acidosis.

Pharmacokinetics

Sodium bicarbonate dissociates in water to provide sodium (Na^+) and bicarbonate (HCO_3^-) ions. Sodium is the principal cation of the extracellular fluid. Bicarbonate is a normal constituent of body fluids and the normal plasma level ranges from 24 to 31 mmol/L. Plasma concentration is regulated by the kidney.

The bicarbonate anion, at the correct concentration of hydrogen ion (H^+) may be converted to carbonic acid (H_2CO_3), then to its volatile form, carbon dioxide (CO_2) which is excreted by the lung. Normally, a ratio of 1:20 (carbonic acid: bicarbonate) is present in the extracellular fluid.

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

INDICATIONS:
Management of Metabolic acidosis, Gastric hyperacidity, As an alkalinization agent for the urine, Treatment of hyperkalemia, Management of overdose of certain drugs, Including tricyclic antidepressants and aspirin.
Metabolic acidosis 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 where a rapid increase in plasma total CO_2 content is crucial. Treatment of metabolic acidosis should be concurrent with measures designed to control the cause of the acidosis.
Urinary alkalinisation in the treatment of certain drug intoxications (i.e. barbiturates, salicylates, lithium, and methyl alcohol) and in the haemolytic reactions requiring alkalinisation of the urine to diminish nephrotoxicity of blood pigments.
Urinary alkalinisation is also used in methotrexate therapy to prevent nephrotoxicity.
Severe diarrhoea is often accompanied by a significant loss of bicarbonate.

CONTRAINDICATIONS:
- Renal failure

- Metabolic alkalosis
- Respiratory alkalosis
- Hypertension
- Oedema
- Congestive heart failure
- History of urinary calculi and coexistent potassium depletion or hypocalcaemia
- Hypernatraemia, hypoventilation or chloride depletion
- In patients at risk of developing diuretic induced hypochloraemic alkalosis
- Eclampsia, aldosteronism.

It is also generally contraindicated in patients with excessive chloride loss from vomiting or continuous gastrointestinal suctioning and in patients at risk of developing diuretic induced hypochloraemic alkalosis.

PRECAUTIONS:

- Whenever respiratory acidosis is concomitant with metabolic acidosis, both pulmonary ventilation and perfusion must be adequately supported to get rid of excess carbon dioxide (CO_2).
- To minimize the risks of pre-existing hypokalaemia and/or hypocalcaemia, these electrolyte disturbances should be corrected prior to initiation of, or concomitantly with, sodium bicarbonate therapy.
- Arterial blood gas analysis, in particular, arterial/venous blood pH and carbon dioxide levels should be performed during the course of sodium bicarbonate treatment to minimize the possibility of overdosage and resultant alkalosis.
- Sodium bicarbonate should be used with caution in patients with cirrhosis.
- Excessively elevated plasma sodium concentrations may cause dehydration of the brain, resulting in somnolence and confusion, which may progress to convulsions, coma, respiratory failure and ultimately death.
- Bicarbonate should be given with caution to patients with type A lactic acidosis (tissue hypoxia). Administration of bicarbonate may limit the available oxygen, increase lactate production, thus, worsen the acidosis.
- Sodium bicarbonate should not be used in the treatment of diabetic ketoacidosis with pH between 6.90 and 7.10.

PREGNANCY CATEGORY: C

Use in Pregnancy

Animal reproduction studies have not been performed with sodium bicarbonate. It is also not known whether sodium bicarbonate can cause foetal harm when administered to pregnant women. Sodium bicarbonate should be used during pregnancy only when clearly needed and the benefits of therapy outweigh the potential risks.

Use in Lactation

It is not known whether sodium bicarbonate is excreted in breast milk. However, problems in humans have not been reported.

DOSAGE AND ADMINISTRATION

Chronic Renal Failure: Oral: Initiate when plasma HCO_3^- <15 mEq/L Start with 20-36 mEq/day in divided doses, titrate to bicarbonate level of 18-20 mEq/L.

Renal Tubular Acidosis: Oral:

Distal: 0.5-2 mEq/kg/day in 4-5 divided doses

Proximal: Initial: 5-10 mEq/kg/day; maintenance: Increase as required to maintain serum

bicarbonate in the normal range

Urine alkalinization: Oral: Initial: 48 mEq (4 g), then 12-24 mEq (1-2 g) every 4 hours; dose should be titrated to desired urinary pH; doses up to 16 g/day (200 mEq) in patients.
<60 years and 8 g (100 mEq) in patients >60 years
Antacid: Oral: 325 mg to 2 g 1-4 times/day

Use in Renal Impairment
Sodium retention and oedema may occur during sodium bicarbonate therapy, especially when the drug is given in large doses or to patients with renal insufficiency, congestive heart failure or those predisposed to sodium retention and oedema. Sodium and water overload may result in hypernatraemia and hyperosmolality. Severe hyperosmolal states may develop during cardiopulmonary resuscitation when excessive doses of sodium bicarbonate are administered. Serum potassium may decrease during sodium bicarbonate therapy leading to hypokalaemia.
Sodium bicarbonate should be used with extreme caution in patients with in patients with renal insufficiency or other oedematous or sodium retaining conditions; especially those with severe insufficiency such as oliguria or anuria; and in patients receiving corticosteroids or corticotropin, since each gram of sodium bicarbonate contains 12 mEq of sodium.

Effects on Laboratory Tests
The high urinary alkalinity sometimes produced by sodium bicarbonate may cause a false positive Labstix test for urinary protein.

INTERACTIONS WITH OTHER MEDICINES:

- Urinary alkalisation will increase the renal clearance of tetracyclines, especially doxycycline, but it will increase the half life and duration of action of basic drugs such as quinidine, amphetamines, ephedrine and pseudoephedrine.
- The addition of sodium bicarbonate to solutions containing calcium should be avoided except where compatibility has been shown. Solutions turning hazy as a result of sodium bicarbonate-calcium admixtures should be discarded.
- Use caution when giving parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotrophin.
- Hypochloraemic alkalosis may occur if sodium bicarbonate is used in conjunction with potassium depleting diuretics such as bumetanide, ethacrynic acid, frusemide and thiazides. Concurrent use in patients taking potassium supplements may reduce serum potassium concentration by promoting an intracellular ion shift.
- Alkalinisation of the urine leads to increased renal clearance of acidic drugs such as salicylates, tetracyclines, (especially doxycycline), barbiturates and tricyclic antidepressants. Conversely, it prolongs the half-life and duration of basic drugs such as quinidine, amphetamines, ephedrine and pseudoephedrine and may result in toxicity.
- Sodium bicarbonate enhances lithium excretion.
- Solutions containing sodium ions should be used with great care, if at all, in patients receiving corticosteroids or corticotropin.
- Hypochloraemic alkalosis may occur if sodium bicarbonate is used in conjunction with potassium depleting diuretics such as bumetanide, ethacrynic acid, frusemide and thiazides. Concurrent use in patients taking potassium supplements may reduce serum potassium concentration by promoting an intracellular ion shift.
- The following drug may have enhanced or prolonged effects due to concomitant administration with sodium bicarbonate: flecainide.
- The following drugs may have decreased effectiveness due to concomitant

administration with sodium bicarbonate: aspirin and other salicylates, barbiturates and lithium.

- The following drugs have been reported to be susceptible to inactivation on mixing with sodium bicarbonate solution: adrenaline HCl, benzyl penicillin potassium, carmustine, glycopyrrolate, isoprenaline HCl and suxamethonium chloride.

ADVERSE EFFECTS:

- Frequency not defined.
- **Cardiovascular:** Cerebral hemorrhage, CHF (aggravated), edema
    - Cerebral oedema has occurred with sodium bicarbonate use and a possibility of intracranial haemorrhage exists.
- **Central nervous system:** Tetany
    - Hyperirritability or tetany may occur caused by rapid shifts of free ionized calcium or due to serum protein alterations arising from the pH changes.
    - Metabolic alkalosis may be accompanied by compensatory hyperventilation, paradoxical acidosis of the cerebrospinal fluid, severe hypokalaemia, hyperirritability or tetany.
- **Gastrointestinal:** Belching, flatulence (with oral), gastric distension
- **Endocrine & Metabolic:** Hypernatremia, hyperosmolality, hypocalcaemia, hypokalemia, increased affinity of hemoglobin for oxygen-reduced pH in myocardial tissue necrosis when extravasated, intracranial acidosis, metabolic alkalosis, milk-alkali syndrome (especially with renal dysfunction)
    - Alkalosis and/or hypokalaemia may result from prolonged use or overcorrection of the bicarbonate deficit, especially in patients with impaired renal function (see **Overdosage**).
    - Hypernatraemia has been reported with sodium bicarbonate use, especially in patients with renal disease.
- **Respiratory:** Pulmonary edema
- Hyperosmolality has also been associated with sodium bicarbonate use.
- Hypercapnia has occurred in patients receiving sodium bicarbonate and with fixed ventilation.

OVERDOSAGE:

Symptoms

Alkalosis is a direct result of overdosage. Excessive administration of bicarbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood changes (hyperirritability), tiredness, shortness of breath, muscle weakness and irregular heartbeat. Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic patients.

Treatment

Administration of sodium bicarbonate should be immediately discontinued. In order to control the symptoms of alkalosis, the patient should rebreath expired air, and the patient treated with intravenous sodium chloride 0.9% and potassium chloride if hypokalaemia is present.

Any accompanying hyperirritability or tetany can be controlled with calcium gluconate. Ammonium chloride may be indicated in severe cases (except in patients with pre-existing hepatic disease).

Treatment of hypernatreamia usually requires water replacement. In some cases, restricted

sodium intake and oral water may be sufficient. If more severe, glucose 5% may be administered by slow intravenous infusion. If total body sodium is too high, loop diuretics combined with an infusion of 5% glucose and potassium supplementation may be necessary.

PRESENTATION
Sodium Bicarbonate 500 mg Tablets

STORAGE
Store below 30°C.
The expiry date (month/year) is stated on the package after EXP.

PACKING- 1*10 TAB

* Public Interest

BIOS LAB PVT. LTD.

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