HOSPIMAX
Maximising Life

SobiMax™

Product Description:

- **SobiMax Injection 8.4%:** 100 mail Vial contains 8.4 gm of Sodium bicarbonate Each mL of solution contains 84.0 mg of sodium bicarbonate which gives 1 mmol or 1 mEq of sodium and 1 mmol or 1 mEq of bicarbonate.
- **SobiMax Oral Solution** (225 ml self-dispensing bottle): Each 15 ml contains Sodium bicarbonate 1000 mg and sodium chloride 10 mg
- **SobiMax 500**: Each film coated tablet contains Sodium Bicarbonate IP 500 mg
- **SobiMax 1000:** Each film coated tablet contains Sodium Bicarbonate IP 1000 mg
- **SobiMax EC 500:** Each enteric coated tablet contains Sodium Bicarbonate IP 500 mg
- **SobiMax EC 1000:** Each enteric coated tablet contains Sodium Bicarbonate IP 1000 mg
- **SobiMax Sachet:** Each sachet contains Sodium Bicarbonate IP 1000 mg

General Information

Healthy kidneys help in maintaining metabolic homeostasis in the body. Although there are several components to metabolism, the kidneys specifically balance acids and bases, helping body maintain a slightly alkaline (basic) pH of around 7.4.

Kidneys excrete daily acid load, derived mostly from the metabolism of amino acids, as phosphoric acid and ammonium. The more acids the body produces, the more phosphoric acid and ammonium the kidneys excrete — thus helping to maintain balance.
When kidney get dysfunction, less of the daily acid load is excreted due to which the blood becomes more acidic. Eventually, an imbalanced state develops called **metabolic acidosis,** which is commonly associated with chronic kidney disease.

This process is a vicious cycle. Chronic kidney disease results in metabolic acidosis, which in turn causes more kidney damage. Additional problems include low bone mineralization, muscle breakdown, insulin resistance, high triglycerides, systemic inflammation, low blood pressure, and malaise.

Metabolic balance has to be corrected by reversing metabolic acidosis is one of the goals in treating chronic kidney disease, and this can be achieved by using sodium bicarbonate.

Sodium bicarbonate is a chemical compound with a formula of NaHCO3. It is a salt composed of sodium ions and bicarbonate ions. Sodium Bicarbonate tablets used as an alkalinizing agent in the treatment of metabolic acidosis.

Sodium bicarbonate also may be used as an alkalinizing agent in advanced cardiovascular life support (ACLS) during cardiopulmonary resuscitation (CPR)

Indication & Usage

Sodium bicarbonate is used for 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.

Also is indicated in severe diarrhea which is often accompanied by a significant loss of bicarbonate. 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.

Dosage and Administration

The dose of Sodium Bicarbonate will be different for different patients.

Usual Adult Dose for Moderate metabolic acidosis is 325 to 2000 mg orally 1 to 4 times a day.

(Patients younger than 60 yr of age, max dose 16 g/day; patients older than 60 yr of age max dose 8 g/day).

One gram provides 11.9 mEq (mmol) each of sodium & bicarbonate

Dose in Paediatric Patient: 1-2 mEq/kg/day (84-168 mg/kg/day) in 2-3 divided doses

SobiMax Injection 8.4%:

- **Cardiac Arrest or Severe Metabolic Acidosis**
- In cardiac arrest, an initial direct intravenous dose of 1 mmol/kg (1 mL/kg of an 8.4% sodium bicarbonate solution) may be given, followed by 0.5 mmol/kg (0.5 mL/kg of an 8.4% sodium bicarbonate solution) at ten minute intervals
- **Children**
- The usual dose is 1 mmol/kg (1 mL/kg of an 8.4% Sodium Bicarbonate Injection) given by slow intravenous injection.
- **Infants (up to 2 years of age)**

- In infants (up to 2 years of age) the solution should be diluted with an equal amount (1:1 ratio) of 5% glucose or water for injections (to make 4.2% sodium bicarbonate solution) for slow intravenous administration and at a dose not to exceed 8 mmol/kg/day.

Intravenous infusion

- The amount of bicarbonate to be given as intravenous infusion to **older children and adults over a 4 to 8 hour period is approximately 2 to 5 mmol/kg of bodyweight,** depending upon the severity of the acidosis as judged by the lowering of the total CO2 content, blood pH and clinical condition of the patient.

Mechanism of action

Sodium bicarbonate is a systemic alkalizer, which increases plasma bicarbonate, buffers excess hydrogen ion concentration, and raises blood pH, thereby reversing the clinical manifestations of acidosis.

It is also a urinary alkalizer, increasing the excretion of free bicarbonate ions in the urine, thus effectively raising the urinary pH. By maintaining an alkaline urine, the actual dissolution of uric acid stones may be accomplished.

Sodium bicarbonate acts as an antacid and reacts chemically to neutralize or buffer existing quantities of stomach acid but has no direct effect on its output. This action results in increased pH value of stomach contents, thus providing relief of hyperacidity symptoms.

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 (H2CO3) and hence to its volatile form, carbon dioxide (CO2) excreted by the lung. Normally a ratio of 1:20 (carbonic acid; bicarbonate) is present in the extra cellular 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.

Pharmacokinetic

Absorption: Well absorbed after oral administration as sodium ion and bicarbonate.
Distribution: Occurs naturally and is confined to the systemic circulation.
Metabolism: None.
Excretion: Filtered and reabsorbed by the kidney; less than 1% of filtered bicarbonate is excreted.

Use in Specific Population

Pregnancy: Safety hasn't been established for use during pregnancy.

Nursing Mother: It isn't known if sodium bicarbonate appears in breast milk. Use cautiously in breast-feeding women.

Paediatric Use: Children up to 6 years of age—Dose must be determined by the doctor.

Geriatric Use: There is no specific information comparing use of sodium bicarbonate in the elderly with use in other age groups.

Contraindication: Sodium Bicarbonate 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, metabolic and respiratory alkalosis; hypocalcemia in which alkalosis may produce tetany, hypertension, convulsions or CHF; when administration of sodium could be clinically detrimental.

Warning & Precaution:

Sodium bicarbonate to be given with doctor consultation if patients has: a certain breathing problem (pulmonary edema), congestive heart failure, severe kidney disease (e.g., inability to make urine), severe liver disease (e.g., ascites, cirrhosis), high sodium levels, and swollen ankles/legs/feet due to retaining water (peripheral edema). If patient has any of the following health problems, doctor consultation is required before using Sodium Bicarbonate: low calcium levels, high blood pressure, heart problems (e.g., irregular heartbeat) and kidney disease.

Because this medication contains salt (sodium), do not use if patient is on a salt-restricted diet.

Drug Interaction:

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, there should be variations in the dose

- Acalabrutinib, Amphetamine, Benzphetamine, Dextroamphetamine
- Digoxin, Elvitegravir, Gefitinib, Ketoconazole, Ledipasvir
- Lisdexamfetamine, Mefenamic Acid, Memantine, Methamphetamine
- Neratinib, Pazopanib, Rilpivirine

Side Effects & Adverse Reactions:

Side effects associated with Sodium bicarbonate which are Frequent urge to urinate, muscle pain or twitching, swelling of feet or lower legs, nausea or vomiting, headache, decreased appetite, unusual tiredness, constipation, dry mouth or increased thirst

Few common adverse reactions associated with Sodium Bicarbonate are Exacerbation of CHF, Rebound hyperacidity, milk-alkali syndrome, Hypernatremia, alkalosis, Extravasations with cellulitis, tissue necrosis, ulceration, venous irritation, tetany or edema.