SOBISIS-EC

Sodium Bicarbonate Enteric Coated Tablet 500 mg

BACKGROUND:

Metabolic acidosis is a common complication of chronic kidney disease (CKD). The pathogenesis associates the lack of bicarbonate production with the accumulation of organic/inorganic acids and the development of tubule-interstitial damage through ammonium retention and complement deposition. The empiric use of oral sodium bicarbonate represents an interesting therapeutic option. The availability of oral sodium, in its diverse forms, represents an inexpensive and simple way of treating an entity that could hasten the progression of kidney disease, as well as protein catabolism, bone disease and mortality.

DESCRIPTION:

- **SOBISIS-EC** is enteric coated Sodium bicarbonate tablet, used for cases of acidosis, or when insufficient sodium or bicarbonate ions are in the blood.
- Sodium bicarbonate is a chemical compound with the formula $NaHCO_3$. It is a salt composed of sodium ions and bicarbonate ions. Metabolic acidosis is a common complication associated with progressive loss of kidney function.

INDICATION:

SOBISIS-EC is indicated for the chronic management of Metabolic Acidosis in CKD patient.

MECHANISM OF ACTION:

Sodium bicarbonate dissociates to provide bicarbonate ions which neutralize hydrogen ions concentration and raises blood and urinary pH

- Alkalizer, systemic-Increases the plasma bicarbonate, buffers excess hydrogen ion concentration, and raises blood pH, thereby reversing the clinical manifestations of acidosis.
- Alkalizer, urinary-Increases the excretion of free bicarbonate ions in the urine, thus effectively raising the urinary pH. By maintaining alkaline urine, the actual dissolution of uric acid stones may be accomplished.

DOSAGE:

The recommended starting dose for moderate metabolic acidosis is 325 to 2000 mg orally 1 to 4 times a day.

Calculation of Dosage:

- 1 mEq $NaHCO_3$ is equivalent to 84 mg; each g of $NaHCO_3$ provides ~12 mEq each of sodium and bicarbonate ions.
- Metabolic acidosis in patients with chronic kidney disease: KDIGO guidelines suggest oral replacement when plasma HCO_3^- concentrations are <22 mEq/L.
- Initial: 15.4 to 23.1 mEq/day in divided doses (eg, 500 mg tablet 2 to 3 times daily); titrate to normal serum bicarbonate concentrations (eg, 23 to 29 mEq/L).

ADVANTAGES:

- **SOBISIS-EC** is GI friendly enteric coated sodium bicarbonate.
- **SOBISIS-EC** helps to reach bicarbonate goal.
- **SOBISIS-EC** delays the progression of kidney disease.
- **SOBISIS-EC** improves the nutritional status.

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BACKGROUND:

The Prevalence of the metabolic acidosis of CKD

Metabolic Acidosis is defined as a serum bicarbonate concentration continually <22 mEq/L in individuals with decreased kidney function. The metabolic acidosis of CKD has been estimated to be present in 2.3% to 13% of individuals with stage 3 CKD and 19% to 37% of individuals with stage 4 CKD.

Adverse Effects of the Metabolic Acidosis of Chronic Kidney Disease

- Increased degradation of muscle protein with muscle wasting
- Dissolution of bone and bone disease
- Progression of chronic kidney disease
- Stimulation of inflammation
- Impairment of insulin secretion and responsiveness
- Stimulation of amyloid accumulation
- Increased risk for death

ORAL ADMINISTRATION OF SODIUM BICARBONATE - A PHARMACEUTICAL TECHNOLOGICAL CHALLENGE:

- Firstly, the drug must not be released in the stomach as the acidic gastric juice would immediately transform bicarbonate into carbon dioxide. The desired therapeutic effect would not be achieved and the produced gas could cause abdominal pain and flatulence.
- Secondly, sodium bicarbonate should be rapidly released from the solid dosage form into the intestinal fluid as residuals of bicarbonate in ileum and colon may cause diarrhoea and flatulence. Both criteria can be fulfilled by enteric-coated dosage forms of sodium bicarbonate.

"Clinical Studies show that around 35% of CKD patients taking raw uncoated sodium bicarbonate therapy cannot tolerate the therapeutic dose need to reach their bicarbonate (TCO_2) goal. The primary reason is excessive bloating, belching or burping and acid reflux."

"Clinical studies have also shown that in people with CKD, raising serum bicarbonate from 19.9 mEq/l to 24mEq/l can slow the progression of kidney disease by 2-3 fold (200-300%)."

SOBISIS-EC - "OVERCOMES ALL THE BARRIERS"

- **SOBISIS-EC** is designed to reduce elevated serum acid levels due to chronic kidney disease, without the GI upset seen with raw uncoated Sodium bicarbonate.
- With Enteric Coating, the release of the sodium bicarbonate in the intestinal tract can be controlled, so that the sodium bicarbonate is more suitable for treating metabolic acidosis, thereby regulating the acid-base balance of body fluid, reducing adverse effects caused by the sodium bicarbonate in the stomach and reducing the administration dosage of the sodium bicarbonate.

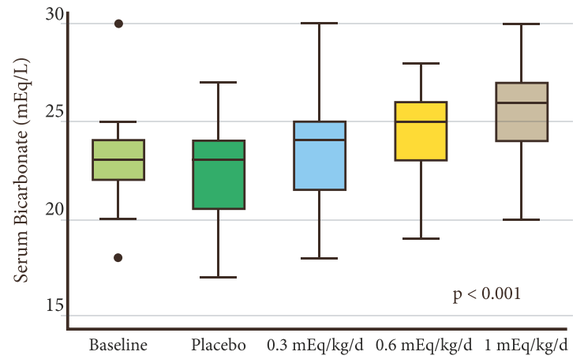
Reference:- Am J Kidney Dis. 2016;67(2):307-317

CLINICAL EVIDENCES

A) Effects of Oral Sodium Bicarbonate in Patients with CKD[1]

Metabolic acidosis contributes to muscle breakdown in patients with CKD

- 20 adults with estimated GFR 15–45 ml/min per 1.73 m^2 and serum bicarbonate 20–24 mEq/L were treated during successive 2-week periods with placebo followed by escalating oral $NaHCO_3$ doses (0.3, 0.6, and 1.0 mEq/kg per day).
- Each 0.1 mEq/kg per day increase in dose produced a 0.33 mEq/L (95% confidence interval=0.23–0.43 mEq/L) higher serum bicarbonate.
- Sit-to-stand time improved after 6 weeks of oral $NaHCO_3$ (23.8 ± 1.4 versus 22.2 ± 1.6 seconds for 10 repetitions)
- Higher $NaHCO_3$ doses were not associated with increased BP or greater edema.



CONCLUSION:

$NaHCO_3$ supplementation produces a dose-dependent increase in serum bicarbonate and improves lower extremity muscle strength after a short-term intervention in CKD patients with mild acidosis.

B) The effect of sodium bicarbonate on cytokine secretion in CKD patients with metabolic acidosis[2]

- Inflammation, which is common in CKD, may be related to acidosis.
- Thirteen patients with CKD 4–5 and acidosis were treated with Oral sodium bicarbonate started at a dose ranging from 1 to 3 g per day based on the initial serum bicarbonate level.
- Serum bicarbonate increased (18.6 ± 0.4 mequiv./l to 21.3 ± 0.3 mequiv./l, P=0.001)
- The secretion of the anti-inflammatory cytokine IL-10 decreased (2.75 ± 0.25 ng/ml to 2.29±0.21 ng/ml, P=0.041)

CONCLUSION:

Sodium bicarbonate decreases IL-10 secretion & so that Correcting metabolic acidosis in CKD during stage of 4-5.

Reference:
1. Clin J Am Soc Nephrol. 2013 May;8(5):714-20
2. Biomed Pharmacother. 2015 Apr;71:98-101