Size = 123x188mm
Print color = Black
Print scheme = Back to Back Printing

Sobisis /Sobisis Forte

(Sodium Bicarbonate Tablets USP 500mg/1000 mg)

COMPOSITION:
Each film coated tablet contains:
Sodium Bicarbonate USP ……500 mg/ 1000 mg
Excipients .....q.s.

DESCRIPTION:
Sodium Bicarbonate is a white, crystalline powder that is commonly used as a pH buffering agent, an electrolyte replenisher, systemic alkalizer and in topical cleansing solutions. Sodium Bicarbonate is the monosodium salt of carbonic acid with alkalinizing and electrolyte replacement properties. Upon dissociation, Sodium Bicarbonate forms sodium and bicarbonate ions. Ion formation increases plasma bicarbonate and buffers excess hydrogen ion concentration, resulting in raised blood pH.

CLINICAL PHARMACOLOGY:
Pharmacodynamics:
Sodium Bicarbonate is a systemic alkalizing agent which, when given orally will increase plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses the clinical manifestations of acidosis.
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 an alkaline urine, the actual dissolution of uric acid stones may be accomplished.

Pharmacokinetics
Absorption: Well absorbed after oral administration as sodium ion and bicarbonate ion.
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.
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.

INDICATIONS:
Sodium Bicarbonate tablets are used for 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. It is also used in severe diarrhoea which is often accompanied by a significant loss of bicarbonate.

DOSAGE & ADMINISTRATION:
Moderate metabolic acidosis: 325 to 2000 mg orally 1 to 4 times a day. One gram provides 11.9 mEq (mmoL) each of sodium and bicarbonate.

CONTRAINDICATIONS:
Sodium Bicarbonate is contraindicated in patients with metabolic or respiratory alkalosis; in those who are losing chlorides by vomiting or from continuous GI suction; in those receiving diuretics known to produce hypochloremic alkalosis; and in patients with hypocalcemia in which alkalosis may produce tetany, hypertension, seizures, or heart failure. Orally administered Sodium Bicarbonate is contraindicated in patients with acute ingestion of strong mineral acids. Use extreme caution when giving drug to patients with heart failure, renal insufficiency, or other edematous or sodium-retaining conditions.

WARNING AND PRECAUTIONS:
Before taking Sodium Bicarbonate, consult your doctor if you have: 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). Because this medication contains salt (sodium), do not use if you are on a salt-restricted diet. During pregnancy, this medication should be used only when clearly needed. This medication may worsen high blood pressure during pregnancy (toxemia of pregnancy). It is unknown if Sodium Bicarbonate tablets are excreted in breast milk. If you are or will be breast-feeding while you are using Sodium Bicarbonate tablets, check with your doctor or pharmacist to discuss the risks to your baby.

DRUG INTERACTION:
Some products that may interact with this drug include: aspirin and other salicylates (such as salsalate), barbiturates (such as phenobarbital), calcium supplements, corticosteroids (such as prednisone), memantine, medications with a special coating to protect the stomach (enteric coating), lithium, quinidine, "water pills" (thiazide diuretics such as hydrochlorothiazide)

ADVERSE EFFECTS:
Alkalosis and/or hypokalemia, cellulitis, with tissue necrosis or sloughing at the site of infiltration, Hyperirritability, Hypernatraemia, Hyperosmolality, chemical cellulitis, with tissue necrosis, tissue calcification, ulceration or sloughing at the site of infiltration. Hyperirritability, Cerebral oedema Hypercapnia.

OVERDOSE:
Sodium Bicarbonate should be stopped in alkalosis, manage the patient according to the degree of alkalosis present. 0.9% sodium chloride injection intravenous may be given; potassium chloride also may 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

STORAGE:
Store at a temperature not exceeding 30°C. Protect from light and moisture.

PRESENTATION:
1)10 tablets in a blister, 10 such blisters are packed in a carton along with the package insert.
2)10 tablets in a blister, 3 such blisters are packed in a carton along with the package insert.

Manufactured By:
Stanford Laboratories Pvt. Ltd.
(A subsidiary company of La Renon Healthcare Pvt. Ltd.)
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