SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1.NAME OF THE MEDICINAL PRODUCT: SOBISIS FORTE (Sodium Bicarbonate Tablets USP 1000 mg)

Strength: 1000 mg

Pharmaceutical form: Tablet

2.QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each Tablet contains 100 mg of Sodium Bicarbonate
For the full list of excipients, see section 6.1.

3.PHARMACEUTICAL FORM: Tablet

White, oval elongated shaped biconvex film coated tablets plain on both sides.

4.CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Age: ≥ 18 years

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.

4.2 Posology and method of 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.

4.3 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.

4.4 Special warnings and precautions for use:

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.

4.5 Interaction with other medicinal products and other forms of 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).

4.6 Fertility, pregnancy, and lactation.

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.

Fertility:

NO FERTILITY DATA AVAILABLE

4.7 Effects on ability to drive and use machines:

There is no information available for effect of Sodium Bicarbonate on ability

to drive and use machine.

4.8 Undesirable 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.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems to the respective national regulatory authorities

4.9 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

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 alkaline urine, the actual dissolution of uric acid stones may be accomplished.

5.2 Pharmacokinetic properties

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.

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 (H2CO3), then to its volatile form, carbon dioxide (CO2) which is excreted by the lung. Normally, a ratio of 1:20 (carbonic acid: bicarbonate) is present in the extracellular fluid.

5.3 Preclinical safety data

The active ingredients in Sobisis Forte Tablets have a well-documented safety record.

6.PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr. No.	Name of Ingredient
1.	Sodium Bicarbonate
2.	Microcrystalline Cellulose PH 102
3.	Microcrystalline Cellulose plain
4.	Pregelatinised Starch
5.	Purified Talc
6.	Magnesium Stearate
7.	Hydroxylpropyl methyl cellulose (C-15)
8.	Titanium Dioxide
9.	Polyethylene Glycol (6000)
10.	Diethyl Phthalate
11.	Isopropyl Alcohol
12.	Methylene Chloride

6.2 Incompatibilities : Not applicable

6.3 Shelf life : 36 Months

6.4 Special precautions for storage : Store at a temperature not exceeding 30°C. Protect from light and moisture.

6.5 Nature and contents of the container: Alu-PVC Blister pack

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

6.6 Special precautions for disposal <and other handling> : Not

applicable

7.MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETING AUTHORIZATION HOLDER

La Renon Healthcare Pvt. Ltd

207-208, ISCON Elegance, Circle-P, Prahlad

Nagar Cross Roads, S.G. Highway, Ahmedabad-

380015, Gujarat, India

Manufactured By:

Stanford Laboratories Pvt. Ltd.

(A subsidiary company of La Renon Healthcare

Pvt. Ltd) 8, Industrial Area, Mehatpur, Dist.

Una, (H.P.) 174315, India.

8.MARKETING AUTHORIZATION NUMBER : H2019/CTD6176/933ER

9.DATE OF FIRST REGISTRATION < 15 Aug 2018> / RENEWAL OF THE REGISTRATION < >

10. DATE OF REVISION OF THE TEXT :19.01.2024