SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> 84 mg/ml oral solution

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains 84 mg of sodium bicarbonate (equivalent to 1 mmol/ml sodium bicarbonate).

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Oral solution.

<Regarding the approval>

1. CLINICAL PARTICULARS
	1. Therapeutic indications

 Sodium bicarbonate is indicated in adults (including elderly) for:

 The treatment of metabolic acidosis arising from a variety of disorders. The dosage must be calculated on an individual basis and is dependent on the acid-base balance and electrolyte status of the patient.

 The short-term symptomatic treatment of mild or transient dyspepsia.

* 1. Posology and method of administration

 *Adults (including elderly):*

 Metabolic acidosis: dosage is calculated on an individual basis and is dependent on acid-base balance and electrolyte status.

 *Dyspepsia:*

 Doses of 12-60 mL (approximately 1-5 g sodium bicarbonate) every 4-6 hours as required.

 *Paediatric population:*

 The efficacy of sodium bicarbonate in children under 18 years of age has not been established. No data are available.

 Method of administration

 For oral use.

 The required dose should be drawn from the container into the graduated syringe using the syringe adaptor.

* 1. Contraindications
* Hypersensitivity to the active substance
* Metabolic or respiratory alkalosis
* Hypocalcaemia
* Hypochlorhydria.
	1. Special warnings and precautions for use

 Sodium bicarbonate should be used with caution in patients with cirrhosis of the liver and patients on low sodium diets.

 Administer with caution to patients suffering from congestive heart failure, hepatic and renal impairment or hypertension.

 This medicine can mask the symptoms of stomach cancer or ulcer.

 Sodium bicarbonate should be given extremely cautiously to patients with eclampsia, aldosteronism or other conditions associated with sodium retention.

 Do not exceed the recommended dose as excess or prolonged use may lead to alkalosis.

 If symptoms persist consult your doctor.

 Caution is recommended in elderly patients (aged from 65 years). Keep all medicines out of the sight and reach of children.

 Since the efficacy of sodium bicarbonate in children under 18 years of age has not been established sodium bicarbonate 84 mg/ml oral solution is not recommended in children.

* 1. Interaction with other medicinal products and other forms of interaction

 Avoid in patients on salt restricted diets and in patients taking corticosteroids. Sodium bicarbonate increases the excretion of lithium.

 The excretion of aspirin and methotrexate is increased and quinidine and ephedrine reduced in alkaline urine.

 Antacids reduce the absorption of antibacterials (for example tetracyclines and rifampicin), antifungals (e.g. ketoconazole), dipyridamole, phenothiazines, chloroquine, phenytoin and penicillamine.

* 1. Fertility, pregnancy and lactation

 Pregnancy

 Animal studies are insufficient with respect to effects on pregnancy, embryonal fetal development, parturition and postnatal development. The potential risk for humans is unknown. Sodium bicarbonate should not be taken during pregnancy unless advised by a doctor to do so.

 Breast-feeding

 The effects of sodium administration during breast-feeding are not known. Sodium bicarbonate should not be taken if breast-feeding unless advised by a doctor to do so.

 Fertility

 The potential risks of sodium bicarbonate on fertility are not known.

* 1. Effects on ability to drive and use machines

 None known.

* 1. Undesirable effects

 Stomach pains and flatulence has been reported. Alkalosis on prolonged use. Sodium supplements may increase blood pressure or cause fluid retention and pulmonary oedema in those at risk. Hypokalaemia may be exacerbated.

 The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

|  |
| --- |
| Metabolism and nutrition disorders* Not known: Alkalosis on prolonged use, fluid retention, hypokalaemia may be exacerbated, loss of appetite (continuing)

Psychiatric disorders* Not known: Mood or mental changes, nervousness or restlessness

Nervous system disorders* Not known: Headache (continuing)

Vascular disorders* Not known: Hypertension, slow breathing, breathing difficulties, fluid on the lungs

Respiratory, thoracic and mediastinal disorders* Not known: Pulmonary oedema

Gastrointestinal disorders* Not known: Pain in the stomach flatulence, spontaneous stomach rupture, nausea, vomiting, unpleasant taste

Skin and subcutaneous tissue disorders* Not known: Swelling of feet or lower legs

Renal and urinary disorders* Not known: Frequent urge to urinate

General disorders and administration site conditions* Not known: Extreme irritability, unusual tiredness or weakness, muscle spasms or cramps
 |

 Reporting of suspected adverse reactions

 Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Health Product Vigilance Center; HPVC, Thai FDA.

* 1. Overdose

 Excessive amounts of this medicine may cause metabolic alkalosis, especially if renal function is impaired. Shortness of breath, muscle weakness, convulsions and coma has been reported in severe cases. sodium overload and hyperosmolarity may also occur.

 Treatment is supportive with appropriate correction of fluid and electrolyte imbalance using sodium free fluids.

1. PHARMACOLOGICAL PROPERTIES
	1. Pharmacodynamic properties

 *Pharmacotherapeutic group:*

 Alimentary tract and metabolism; Drugs for acid related disorders; Antacids; Antacids with sodium bicarbonate, ATC code: A02AH

 Sodium bicarbonate is used for a variety of therapeutic purposes including the correction of metabolic acidosis and as an antacid for the treatment of dyspepsia. Sodium bicarbonate causes neutralisation of gastric acid with the production of carbon dioxide.

 Sodium bicarbonate therapy increases plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses clinical manifestations of metabolic acidosis.

* 1. Pharmacokinetic properties

 Absorption

 Sodium bicarbonate is readily absorbed from the gastro-intestinal tract.

 Distribution

 Sodium bicarbonate is present in all body fluids. Sodium bicarbonate causes neutralization of gastric acid with the production of carbon dioxide.

 Biotransformation

 Sodium bicarbonate is not significantly metabolized.

 Elimination

 Any bicarbonate not involved in the gastric acid neutralisation reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine. The urine is rendered alkaline and there is an accompanying dieresis.

* 1. Preclinical safety data

 No relevant information additional to that contained elsewhere in the SPC.

1. PHARMACEUTICAL PARTICULARS
	1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

 Not applicable.

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>