SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 500 mg Capsules, Hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Sodium Bicarbonate 500 mg. Equivalent to 137 mg of Sodium.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules, hard (Capsules)
White, Size “0”, hard gelatin capsules with axial print “RL” on the body and axial print “01” on the cap.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Bicarbonate is intended for the treatment of dyspepsia in dose of 1-5g. It may also be used to treat metabolic acidosis arising from a variety of disorders as well as severe respiratory acidosis. The dosage must be calculated on an individual basis and is dependent on the acid-base balance and electrolyte status of the patient.

4.2 Posology and method of administration

For oral administration. To be swallowed whole with a drink of water.

Adults

Dyspepsia: 1g – 5g when required.

Metabolic Acidosis: The dosage is dependent upon the acid-base balance and electrolyte status of the patient and must be calculated on an individual basis.

Children

Not recommended.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

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

Sodium bicarbonate should be used with caution by patients on low sodium diets.

Sodium bicarbonate should be used with caution by patients with cirrhosis of the liver.

If symptoms persist consult your doctor.

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

Caution in the elderly.

Keep all medicines out of the reach of children.

4.5 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.

4.6 Fertility, pregnancy and lactation

The safety of Sodium Bicarbonate during pregnancy and lactation has not been established. May be used if the usual precautions are followed and the anticipated benefits outweigh any risks.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Stomach pains and flatulence have 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.

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 yellow card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

4.9 Overdose

Metabolic alkalosis may occur particularly if renal function is impaired. In severe cases shortness of breath, muscle weakness, convulsions, coma have been reported.
Sodium overload and hyperosmolality may also occur.

Treatment should be supportive with appropriate correction of fluid and electrolyte imbalance using sodium-free fluids.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A02AH Antacids with Sodium Bicarbonate.

The normal concentration range of bicarbonate in plasma is 22 to 32 mmol per litre. The average intake of bicarbonate in the diet is negligible and very little is excreted in the urine under normal conditions; bicarbonate ions formed in the body are excreted in biliary, intestinal, pancreatic and salivary fluids. If bicarbonate is administered therapeutically thus increasing the plasma-bicarbonate concentration above the normal range then compensatory renal mechanisms come to play and bicarbonate is excreted in the urine.

5.2 Pharmacokinetic properties

Oral administration of sodium bicarbonate causes neutralisation of gastric acid with the production of carbon dioxide. The remaining bicarbonate is absorbed and, in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted, along with sodium ions, in the urine which is rendered alkaline and there is an accompanying diuresis.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Magnesium Stearate

Capsule shell:
Gelatin
Titanium Dioxide (E171)

Printing ink:
Shellac (E904)
Black Iron Oxide (E172)
Potassium Hydroxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and contents of container

Primary Packaging Material: White, opaque PVC/PVdC 250µm / 40 gsm with a 20 µm lacquered aluminium foil.

Secondary Packaging Material: Printed Carton containing blister packs of 56 Capsules and a leaflet.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Relonchem Limited,
Cheshire House, Gorsey Lane, Widnes, WA8 0RP, UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 20395/0124

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/09/2012

10 DATE OF REVISION OF THE TEXT

13/08/2020