

## **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**

Avoid in patients on salt restricted diets.

Administer with caution in patients suffering from heart failure, hypertension, hepatic or renal impairment.

Warning: Do not take more medicine than the label tells you to.

Prolonged use should be avoided.

Caution advised in elderly patients. Although a reduction of the normal adult dose is not considered necessary, sodium retention could occur if there is concomitant impaired cardiac or renal function.

## **4.5 Interaction with other medicinal products and other forms of interaction**

Sodium bicarbonate increases the excretion of lithium, resulting in reduced plasma lithium concentration.

Antacids reduce the absorption of antibacterials (eg. tetracycline, rifampicin) and antifungals (itraconazole and ketoconazole). They also reduce the absorption of dipyridamole, phenothiazines, chloroquine, hydroxychloroquine, phenytoin, gabapentin, bisphosphonates, penicillamine, captopril, enalapril and possibly other ACE inhibitors.

Antacids also increase the excretion of aspirin and methotrexate and reduce the excretion of ephedrine and quinidine in alkaline urine (occasionally plasma concentrations may increase).

#### 4.6 Fertility, pregnancy and lactation

May be used in pregnancy and lactation if the usual precautions are followed and the anticipated benefits outweigh any risks, however as with all medicines best avoided unless considered essential.

#### 4.7 Effects on ability to drive and use machines

None known.

#### 4.8 Undesirable effects

Adverse reactions are listed by body system and by frequency, using the following convention: very common ( $\geq 1/10$ ); common ( $\geq 1/100$ ,  $< 1/10$ ); uncommon ( $\geq 1/1000$ ,  $< 1/100$ ); rare ( $\geq 1/10,000$ ,  $< 1/1,000$ ); very rare ( $< 1/10,000$ ), and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions
Gastrointestinal disorders	Not known	Stomach pain Flatulence
Metabolism & nutrition disorders	Not known	Alkalosis (with prolonged use) Fluid retention* Hypokalaemia (exacerbation of)
Investigations	Not known	Increased blood pressure*
Respiratory, thoracic & mediastinal disorders	Not known	Pulmonary oedema*

\*Sodium supplements may cause these effects in those at risk.

#### 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### 4.9 Overdose

Hypokalaemia and metabolic alkalosis may occur especially if renal function is impaired. In severe cases there have been reports of mood changes, shortness of breath, muscle weakness, tiredness, irregular heartbeat, convulsions and coma. Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic patients. Excessive doses of sodium salts may cause sodium overloading and hyperosmolality to occur. Treatment of metabolic alkalosis should be supportive with appropriate correction of fluid and electrolyte imbalance. Calcium gluconate may be given. An intravenous infusion of ammonium chloride can be used in severe alkalosis, except in patients with pre-existing hepatic disease.

## **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 not involved in the above reaction 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**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **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 250 $\mu$ m / 40 gsm with a 20  $\mu$ m 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**

02/12/2024

**10     DATE OF REVISION OF THE TEXT**

02/12/2024