SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 500 mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Sodium Bicarbonate 500 mg.
Each tablet contains approximately 137 mg Sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A white, round biconvex tablet, "REKAH" engraved on one size, plain on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Bicarbonate is used for relief in cases of hyperacidity in the stomach.

4.2 Posology and method of administration

Posology

Adults
1-4 tablets, 4 times daily *(*0.5g – 8g), as needed.
Paediatric population
Not recommended for use under 6 years of age.

Method of administration
Oral. To be swallowed with a glass of water.
For ease of swallowing, the tablet may be halved or crushed, for immediate use.
No information is available regarding the uniformity of split halves of the tablet.

4.3 Contraindications

Hypersensitivity to the active substance 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 (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, < 1/100); rare (≥ 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

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

mediastinal disorders		

*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. Any
suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il.

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 plasmabicarbonate in 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

Starch, Magnesium Stearate, Ac-Di-Sol (Croscarmellose sodium), Acacia, Talc.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

- Store in a dry place and below 25ºC.
- The medicine can be used for up to 60 days after the package is first opened, and no later than the expiry date (exp. Date) that appears on the package.
- Keep the container tightly closed after each use to protect from moisture.
- Store in the original container.

6.5 Nature and contents of container

HDPE Securitainer, containing 100 tablets along with a desiccant (moister absorbent). Do not take the desiccant out of the package.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St., Holon, 5881904, Israel.

8 MARKETING AUTHORISATION NUMBER(S)

022-07-23524-00

9 DATE OF REVISION OF THE TEXT

Revised in August 2023 according to MOH guidelines.