SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 500 mg Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Sodium Bicarbonate 500 mg.

Each Capsule contains 137mg of sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

White, size 1, hard gelatin capsule printed with “NaB 500”.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Bicarbonate is used for the treatment of dyspepsia.

4.2 Posology and method of administration

Posology

Adults
Dyspepsia: 1g – 5g when required.

Paediatric population
Not recommended for use in this population.

Method of administration

Oral. To be swallowed whole (do not chew) with a drink of water.

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 exceed the stated dose.

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.

Information about excipients:

This medicinal product contains 137mg sodium per 500mg capsule, equivalent to 6.85% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Talk to your doctor or pharmacist if you need 2 or more capsules daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

This medicinal product contains 137mg sodium per dose, equivalent to 6.85% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 68% of the WHO recommended maximum daily intake for sodium. Sodium bicarbonate is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

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
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 & 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 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 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

Microcrystalline Cellulose
Magnesium Stearate

Capsule Shell:
Gelatin
Water
Titanium Dioxide (E171)

Printing ink:
Shellac
Black Iron Oxide (E172)
Propylene Glycol (E1520)
Ammonium Hydroxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°c. Keep the container tightly closed.
Store in the original container.

6.5 Nature and contents of container

PP tablet containers with PE caps containing 56 or 100 capsules.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Kent Pharma UK
Limited, 2nd Floor
Connect 38, 1 Dover Place, Ashford
Kent, England, TN23 1FB.

8 MARKETING AUTHORISATION NUMBER(S)

PL 51463/0137

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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03/12/2025