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 excipients, see 6.1.

3 PHARMACEUTICAL FORM

Capsules, hard (Capsules)

White, Size “0”, hard gelatin capsules with axial print “KPL” 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. It may also be used to treat metabolic acidosis.

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 any of the capsule ingredients.

4.4 Special warnings and precautions for use

Avoid in patients on low sodium and salt restricted diets.

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

Caution is advised in elderly patients.

Prolonged use should be avoided. If symptoms persist consult your doctor.

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

4.5 Interaction with other medicinal products and other forms of interaction

Antacids increases the excretion of lithium, resulting in reduced plasma lithium concentration. Avoid in patients taking corticosteroids. The excretion of aspirin and methotrexate is increased and quinidine and ephedrine reduced in alkaline urine.

Antacids reduce the absorption of ACE inhibitors (e.g. captopril, enalapril and fosinopril and possibly others), antibacterials (e.g. rifampicin and tetracycline), antiepileptics (gabapentin and phenytoin), antifungals (itraconazole and ketoconazole). They also reduce the absorption of fexofenadine, chloroquine, hydroxychloroquine, phenothiazines, sulpiride, amprenavir, tipranavir, bile acids, bisphosphonates, digoxin, deflazacort, mycophenolate, dipyridamole, rosuvastatin, penicillamine, levothyroxine and lansoprazole.

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, 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

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.

4.9 Overdose

Hypokalaemia and metabolic alkalosis may occur particularly if renal function is impaired. In severe cases there have been reports of shortness of breath, muscle weakness, convulsions, coma, sodium overloading, hyperosmolality and gastric damage.

Treatment should be supportive with appropriate correction of fluid and electrolyte imbalance.

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

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

6.1 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

Athlone Pharmaceuticals Limited

Ballymurray,

Co. Roscommon,

Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 30464/0063

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/09/2012

10 DATE OF REVISION OF THE TEXT

09/04/2013