SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 500mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Bicarbonate 500mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard

Size 1 white capsule either printed "SDB 500" and twin triangle logo or unmarked.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium bicarbonate is indicated in adults. It is used to treat dyspepsia in doses of 1-5 g. It may also be used for the treatment of 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

Posology

Adults
Dyspepsia: 1 g to 5 g (2 to 10 capsules) when required.
Metabolic acidosis: dosage is calculated on an individual basis and is dependent on acid-base balance and electrolyte status.

Paediatric population
Not recommended.

Method of administration
Oral

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.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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 Pregnancy and lactation

The safety of Sodium Bicarbonate during pregnancy and lactation has not been established but it may be used during this period 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 has 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 especially if renal function is impaired. In severe cases shortness of breath, muscle weakness, convulsions and coma have been reported. Sodium overload and hyperosmolarity may also occur. Treatment is supportive with appropriate correction of fluid and electrolyte imbalance using sodium-free fluids.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids with sodium bicarbonate, ATC code: A02AH

The normal concentration range of bicarbonate in plasma is 22 to 32mmol 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 is concentration above the normal range then compensatory renal mechanisms come into play and bicarbonate is excreted in the urine.

5.2 Pharmacokinetic properties

Administration of sodium bicarbonate by mouth causes neutralisation of gastric acid with the production of carbon dioxide. sodium bicarbonate not involved in that reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma,

bicarbonate ions are excreted in the urine along with sodium ions; the urine is rendered alkaline and there is an accompanying diuresis.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Colloidal silicon dioxide
Magnesium stearate
Titanium dioxide (E171)
Gelatin

Printing ink:
Shellac
Black iron oxide (E172)
Propylene glycol (E1520)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Each container consists of a polypropylene tubular container with an open end equipped to accept a polyethylene closure, with a tamper-evident tear strip, and is of

the appropriate size to accommodate 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 250, 500 or 1,000 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited
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Hampden Park
Eastbourne
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BN22 9AG

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/1423

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/03/2009

10 DATE OF REVISION OF THE TEXT

07/08/2019