Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bisodol Antacid Chewable TabletsCalcium Carbonate 522mgMagnesium Carbonate Light 68mgSodium Hydrogen Carbonate 64mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

64 mg of Sodium Hydrogen Carbonate
522 mg of Calcium Carbonate
68 mg of Magnesium Carbonate, Light

Excipients with known effect:
Each chewable tablet also contains 538.3mg of sucrose
Each chewable tablets also contains 18mg of sodium

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet
Circular, smooth white bevel-edged tablet marked Bisodol on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the relief of symptoms of indigestion, dyspepsia, heartburn, acidity and flatulence.

4.2 Posology and method of administration

Posology
Adults
Two tablets as required.

Paediatric population
Children under 12 years: not recommended

Do not take more than 12 tablets in 24 hours.

Method of administration

Bisodol Chewable Tablets are to be administered orally

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Hypophosphataemia. Avoid in patients with renal failure.

Hypercalcaemia and hypercalciuria.

4.4 Special warnings and precautions for use

- Magnesium salts may cause central nervous depression in the presence of renal insufficiency.
- Persons with kidney disease or receiving medical treatment should consult their doctor before using.
- Prolonged use should be avoided. If the symptoms persist, medical advice should be sought.
- Do not exceed the stated dose except on medical advice.
- Ingestion of large amounts of antacid tablets may cause milk-alkali syndrome.
- Bisodol contains sucrose: 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 interactions

As with other antacids, Bisodol Antacid Chewable Tablets may form complexes with certain drugs e.g. tetracyclines, digoxin and vitamins resulting in decreased absorption. Bisodol Antacid Chewable Tablets should not be administered within two hours of taking such drugs. Bisodol Antacid Chewable Tablets can also impede the absorption of phosphates.

4.6 Fertility, pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy/embryonal/foetal development/parturition and postnatal development.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Calcium salts can have a constipating effect and magnesium salts can have a laxative effect.
The specific mixture of antacids is intended to avoid the lower gastrointestinal effects seen with a single antacid preparation. No side effects are associated with sodium bicarbonate except when taken in excess. Rebound hyperacidity may occur with prolonged usage.

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 HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Chronic intake can lead to hypercalcaemia, hypercalciuria, nephrolithiasis, metabolic alkalosis and renal insufficiency. Acid rebound may also occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium bicarbonate, calcium carbonate and magnesium carbonate are antacids. They act by neutralising the hydrochloric acid produced by the stomach and thus reducing gastric and duodenal irritation.

5.2 Pharmacokinetic properties

Calcium Carbonate

Calcium carbonate is converted to calcium chloride by gastric acid. Some of the calcium is absorbed from the intestines but about 85% is reconverted to insoluble calcium salts such as the carbonate and is excreted in the faeces.

Magnesium Carbonate

Magnesium carbonate reacts with gastric acid to form soluble magnesium chloride and carbon dioxide in the stomach. Some magnesium is absorbed but is usually excreted rapidly in the urine.

Sodium Bicarbonate

Administration of sodium bicarbonate by mouth causes neutralisation of gastric acid with the production of carbon dioxide. 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, which is rendered alkaline with an accompanying diuresis.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin soluble
Maize starch
Sucrose
Calcium stearate
Peppermint Essential Oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Packsize of 100 contained in cellophane over wrapped carton of 5 rolls of 20 tablets in wax laminated foil with paper labels.

Packsize of 30 contained in cellulose over wrapped shell and slide cartons.

Packsize of 20 contained in wax laminated foil with paper label.

Packsize of 30 contained in a polypropylene container with a polypropylene lid.
Not all packsizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/071/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

April 2022