Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bisodol Extra Strong Mint Chewable Tablets
Calcium carbonate 522mg
Magnesium carbonate light 68mg
Sodium hydrogen carbonate 64mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:		
Calcium carbonate	522	mg
Magnesium carbonate light	68	mg
Sodium hydrogen carbonate	64	mg

Excipients with known effect:
Each chewable tablet also contains sucrose 538.1mg
Each chewable tablet also contains sodium 18mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
Circular, smooth, chewable tablet with bevelled edges and impressed ‘Bisodol ESM’ 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
One or 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 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.
- This medicinal product contains sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
- This medicinal product contains 18mg sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

As with other antacids, Bisodol Extra Strong Mint Chewable Tablets may form complexes with certain drugs e.g. tetracyclines, iron salts, vitamins and digoxin, resulting in decreased absorption. Bisodol Extra Strong Mint Chewable Tablets should not be administered within two hours of taking such drugs. Bisodol Extra Strong Mint 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

Not applicable.

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 single antacid preparations. No side effects are associated with sodium bicarbonate except when taken in excess.

Rebound hyperacidity may occur with prolonged usage.

Magnesium salts may cause central nervous depression in the presence of renal insufficiency.

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, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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. 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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin Sodium
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^{o}C.
Keep the container tightly closed.

6.5 Nature and contents of container

Polypropylene containers with a polypropylene lid, containing 30 tablets.

Wax laminated foil rolls with paper label, containing 20 tablets.

Wax laminated foil rolls with paper label in a cardboard outer carton, containing 5 rolls of 20 tablets.

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

PA1986/070/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 August 1999

Date of last renewal: 23 August 2009

10 DATE OF REVISION OF THE TEXT

August 2018