Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Peppermint Chewable Tablets Sodium alginate 250mg Sodium hydrogen Carbonate 133.5mgCalcium Carbonate 80mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sodium alginate 250 mg, sodium hydrogen carbonate 133.5 mg and calcium carbonate 80 mg.

Excipients: Aspartame (E951) 3.75 mg per tablet.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.
An off-white to cream, slightly mottled tablet.

Emboss obverse - sword and circle
Emboss reverse - G250

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals or during pregnancy, or in patients with symptoms related to oesophagitis.

4.2 Posology and method of administration

Posology

Adults and children 12 years and over: Two to four tablets after meals and at bedtime (up to four times per day).

Children under 12 years: Should be given only on medical advice.

Duration of treatment:
If symptoms do not improve after seven days, the clinical situation should be reviewed.

Special patient groups

Elderly: No dose modifications necessary for this age group.

Hepatic Impairment: No modifications necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary (See section 4.4)

Method of administration
For oral use, after being thoroughly chewed.

4.3 Contraindications

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to sodium alginate, sodium bicarbonate, and calcium carbonate or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If symptoms do not improve after seven days, the clinical situation should be reviewed.
Sodium: This medicinal product contains 253 mg sodium (11 mmol) per 4 tablet dose, equivalent to 12.65% of the WHO recommended maximum daily intake for sodium.
The maximum daily dose of this product is equivalent to 50.6% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive cardiac failure and renal impairment).
Each four-tablet dose contains 320 mg (3.2 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
This medicinal product contains 3.75 mg aspartame in each tablet. Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalaine. Due to its aspartame content this medicinal product should not be given to patients with phenylketonuria.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose, malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
For children below 12 years, please see section 4.2.

4.5 Interaction with other medicinal products and other forms of interactions

A time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, estramustine and bisphosphonates (diphosphonates). See section 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Clinical studies in more than 500 pregnant women as well as a large amount of data from post-marketing experience indicate no malformative nor feto/ neonatal toxicity of the active substances.

Gaviscon can be used during pregnancy, if clinically needed.

Breast-feeding:

No effects of the active substances have been shown in the breastfed newborns/infants of treated mothers. Gaviscon can be used during breast-feeding.

Fertility:

Clinical experiences have shown that at therapeutic doses no effects on human fertility are anticipated.

4.7 Effects on ability to drive and use machines

Gaviscon has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions have been raked under headings of frequency using the following convention: Very rare: <1/10,000

System Organ Class	Frequency	Adverse Event
Immune system disorders	Very rare (<1/10,000)	Anaphylactic and anaphylactoid reactions Hypersensitivity reactions such as urticaria
Respiratory, thoracic and mediastinal disorders	Very rare (<1/10,000)	Respiratory effects such as bronchospasm

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 Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, 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

Symptoms: The patient may experience abdominal discomfort and may notice abdominal distension.
Management: In the event of overdose symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) ATC code: A02BX13.

On ingestion the medicinal product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents effectively impeding gastro-oesophageal reflux. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect.

5.2 Pharmacokinetic properties

The mechanism of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

There are no non-clinical data of relevance to the prescriber which are additional to those already stated in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Peppermint flavour

Macrogol 20,000

Mannitol (E421)

Copovidone

Aspartame (E951)

Acesulfame potassium (E950)

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Unprinted, glass-clear, thermoformable laminate of uPVC/PE/PVdC with aluminium foil lidding blisters packed into cartons.

Blister pack containing 4, 6 or 8 individually sealed tablets.

Larger packs (16, 24, 32, 48 and 64) will be made up of multiples of the above units and packed into cartons.

Pack sizes 4, 6, 8, 16, 24, 32, 48 or 64 tablets

Polypropylene container containing 8, 12, 16, 18, 20, 22 or 24 tablets.

Multiple packs 32 (2 x 16), 36 (2 x 18), 40 (2 x 20), 44 (2 x 22) or 48 (2 x 24) will be packed into cartons.
Single packs 8, 12, 16, 18, 20, 22 or 24 tablets will be packed into cartons.

Pack sizes 8, 12, 16, 18, 20, 22 24, 2 x 16, 2 x 18, 2 x 20, 2 x 22 or 2 x 24 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/015/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 December 2004

Date of last renewal: 5 October 2013

10 DATE OF REVISION OF THE TEXT

December 2020