SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Peppermint Tablets 500.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sodium alginate 500 mg, sodium hydrogen carbonate 267 g and calcium carbonate 160 mg.

Excipients with known effect: Aspartame (E951) 7.50 mg per tablet.
Sodium 126.5 mg (5.5 mmol) per tablet

3. PHARMACEUTICAL FORM

Chewable tablet.

An off-white to cream, slightly mottled tablet.

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 reflux oesophagitis.

4.2 Posology and method of administration

Posology

Adults and children 12 years and over: One to two tablets after meals and at bedtime.

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).

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.

This medicinal product contains 126.5 mg sodium per tablet, equivalent to 6.3 % 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 is based on a two-tablet dose taken four times per day.

This medicinal product is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

Each tablet contains 160 mg (1.6 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

This medicine contains 7.5 mg aspartame in each tablet. Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine. 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 sucrase-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 interaction

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, penicillamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, estramustine and biphosphonates (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 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 ranked under headings of frequency using the following convention: Very Rare ≤1/10,000

System Organ Class	Frequency	Adverse Event
Immune System Disorders	Very rare	Anaphylactic and anaphylactoid reactions.

		Hypersensitivity reactions such as urticaria
Respiratory, Thoracic and Mediastinal Disorders	Very rare	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 the Yellow Card Scheme at: http://www.mhra.gov.uk/yellowcard

4.9. Overdose

Symptoms
The patient may experience abdominal discomfort and may notice abdominal distention.

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 : A02BX

On ingestion the medicinal product react 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

No pre-clinical findings of any relevance to the prescriber have been reported.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Peppermint flavour
Macrogol 20,000
Mannitol (E421)
Aspartame (E951)
Magnesium stearate
Copovidone
Acelsulfame potassium

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

White, rigid, injection-moulded, polypropylene cylindrical container with snap-bead neck finish packed into cartons.

Container containing 20, 40 or 60 tablets. Pack sizes: 20, 40, 60 and 80 chewable tablets.

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

Blister containing six individually sealed tablets. Pack sizes: 12 and 24 chewable tablets.

Not all pack sizes may be marketed.

6.6. Instruction for use and handling (and disposal)

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited
Dansom Lane
Hull
HU8 7DS
United Kingdom.

8. MARKETING AUTHORISATION NUMBER(S)

PL 00063/0136

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/10/2008

10 DATE OF REVISION OF THE TEXT

24/03/2021