SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Peppermint Flavour Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with with known effect:
Aspartame (E951)

For excipients, see Section 6.1.

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

For oral use, after being thoroughly chewed.

Adults and children 12 years and over: Two to four tablets after meals and at bedtime.

Elderly: No dose modifications necessary for this age group.

Hepatic Impairment: No dose modification 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 the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

If symptoms do not improve after 7 days, the clinical situation should be reviewed.

This medicinal product contains 235 mg (11 mmol) of sodium per four-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 heart 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.

Due to its aspartame content this product should not be given to patients with phenylketonuria.

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, biphosphonates (diphosphonates) and estramustine. See also 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:
There is a lack of robust pre-clinical data available regarding the effects of alginate on fertility; limited studies have not reported any negative effects on parental or offspring fertility or reproduction.

Clinical data do not suggest that Gaviscon has an effect on human fertility.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention: very common (1/10), common (1/100 and <1/10), uncommon (1/1000 and <1/100), rare (1/10,000 and <1/1000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

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: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Symptoms are likely to be minor; some abdominal discomfort may be experienced.

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 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, quickly and effectively impeding gastro-oesophageal reflux, for up to 4 hours. 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

Non-clinical data reveal no special hazard for humans.

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

2 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 (2 x 16, 2 x 18, 2 x 20, 2 x 22 or 2 x 24) 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

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 00063/0627

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/10/2024

10 DATE OF REVISION OF THE TEXT

21/10/2024