SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Gaviscon Double Action Mint

2. Qualitative and quantitative composition

Each 10 ml dose contains Sodium alginate 500 mg, Sodium bicarbonate 213 mg and Calcium carbonate 325 mg.

Excipient(s) with known effect:
Methyl parahydroxybenzoate E218
Propyl parahydroxybenzoate E216
Sodium

For a full list of excipients, see Section 6.1.

3. Pharmaceutical form

Oral suspension.

Opaque, off-white to cream viscous suspension.

4. Clinical particulars

4.1 Therapeutic indications

Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy, and for symptoms of excess stomach acid (hyperacidity). Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

4.2 Posology and method of administration

For oral administration.

Adults and children 12 years and over: 10–20 ml after meals and at bedtime, up to four times per day.

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

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

Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients listed in section 6.1. This product should not be used in patients with moderate or severe renal insufficiency

4.4 Special warnings and precautions for use

This medicinal product contains 255.76 mg (11.12 mmol) sodium per 20 ml dose, equivalent to 12.79 % of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 51.15% 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 20 ml contains 260 mg (6.5 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

If symptoms persist, or treatment is required for more than 7 days continuously, medical advice should be sought.

As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions.

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed)

4.5 Interaction with other medicinal products and other forms of interaction

Due to the presence of calcium and carbonates which act as an antacid, a time-interval of 2 hours should be considered between intake of this product and the administration of other medicinal

products, especially H2-antihistaminics, tetracyclines, digoxine, fluoroquinolones, iron salts, thyroid hormones, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, diphosphonates, and estramustine. See also section 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy

Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of Gaviscon on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience the medicinal product may be used during pregnancy, if clinically needed.

Breastfeeding

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

Fertility

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

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Adverse events which have been associated with sodium alginate, sodium bicarbonate and calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: 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); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Event
Immune System Disorders	Very rare	Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.
Metabolism and Nutritional Disorders	Not known	Alkalosis[1], acid rebound[1], Hypercalcaemia[1], Milk-alkali Syndrome[1]

Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Not known	Constipation[1]

Description of Selected Adverse Reactions

[1] Usually occurs following larger than recommended dosages.

4.9 Overdose

Symptoms

Symptoms are likely to be minor in acute overdose; some abdominal distension may be noticed. Milk-alkali syndrome has occurred in individuals taking large doses of calcium carbonate per day for prolonged periods.

Management

In the event of overdose symptomatic treatment should be given.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: A02BX, other drugs for peptic ulcer and gastro-oesophageal reflux disease.

The medicinal product is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate.

On ingestion, the medicinal product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and studies have shown that the raft interacts with and caps the acid pocket in the stomach, reducing oesophageal acid exposure.

The raft floats on the stomach contents effectively impeding gastro-oesophageal reflux, for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect. In addition in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within it structure, further protecting the oesophagus from these gastric components

Calcium carbonate neutralises gastric acid to provide fast relief from indigestion and heartburn. This effect is increased by the addition of sodium bicarbonate which also has a neutralising action. The total neutralising capacity of the product at the lowest dose of two tablets is approximately 10mEqH+.

5.2 Pharmacokinetic properties

The mode 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

Carbomer 974P

Methyl parahydroxybenzoate E218

Propyl parahydroxybenzoate E216

Saccharin sodium

Peppermint Flavour

Sodium hydroxide

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

Use within six months of opening.

6.4 Special precautions for storage

Store below 30°C. Do not freeze or refrigerate.

6.5 Nature and contents of container

- A cardboard outer carton containing unit dose stick pack style sachets. Pack sizes: 2,4,12 sachets/carton. Each sachet contains 10 ml of Gaviscon. The sachets are composed of polyester, aluminium and polyethylene.
- Amber glass bottles with a polypropylene cap with a polyethylene tamper-evident band lined with expanded polyethylene wad and containing 150 ml.

6.6 Special precautions for disposal and other handling

No special requirement.

7. Marketing authorisation holder

Reckitt Benckiser (Thailand) Limited, Bangkok, Thailand

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

Date of first authorisation:

Date of latest renewal:

10. Date of revision of the text

16/10/2020