SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Double Action Aniseed.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml dose contains sodium alginate 500 mg, sodium bicarbonate 213mg and calcium carbonate 325 mg.

Excipient(s) with known effect:
Methyl parahydroxybenzoate (E218) 40 mg/ 10ml

Propyl parahydroxybenzoate (E216) 6 mg/10ml

Sodium 127.88 mg (5.56 mmol) / 10ml

Benzyl Alcohol* 1.05 mg/10ml *present in fennel flavour

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.

4.4 Special warnings and precautions for use

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.

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

Excipient warnings:

This medicinal product contains 127.88 mg sodium per dose, equivalent to 6.4 % 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 (6.5mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

This medicine contains 1.05 mg benzyl alcohol (from Fennel flavour) per 10 ml. Benzyl alcohol may cause allergic reactions.

Large amounts of benzyl alcohol can build up in the body and may cause side effects (called "metabolic acidosis"). This should be taken into consideration by patients who have a liver or kidney disease or are pregnant or breast-feeding.

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 Events
Immune System Disorders	Very Rarely	Anaphylactic reaction, anaphylactoid reaction. 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 Rarely	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Not Known	Constipation[1]

Description of Selected Adverse Reactions
[1] Usually occurs following larger than recommended dosages.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 overdosage 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.

6.1 List of excipients

Carbomer

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Saccharin sodium

Benzyl Alcohol*present in fennel 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

Do not store above 30°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Amber glass bottles or Pink coated Amber glass bottles

With a polypropylene cap with a polyethylene tamper-evident band lined with expanded polyethylene wad.

Pack sizes: 150, 200, 250, 300, 500 and 600 ml.

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 00063/0543.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/06/2008 / 07/08/2019

10 DATE OF REVISION OF THE TEXT

09/02/2024