SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Original Aniseed Relief.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Gaviscon Original Aniseed Relief contains 250 mg sodium alginate, 133.5 mg sodium bicarbonate and 80 mg calcium carbonate per 5 ml.
Excipient(s) with known effect:
Methyl parahydroxybenzoate E218: 40 mg/ 10ml
Propyl parahydroxybenzoate E216: 6 mg/10ml

Benzyl alcohol* (1.1 mg/10ml)
Sodium 142.6 mg (6.2 mmol)/ 10ml

*present in fennel flavour

For excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

An opaque, pink suspension with the odour and flavour of fennel.

4 Clinical Particulars

4.1. Therapeutic Indications

Gastric reflux, heartburn, flatulence associated with gastric reflux, heartburn of pregnancy, all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.

4.2 Posology and method of administration

For oral administration.

Adults and children over 12 years: 10-20ml after meals and at bedtime.

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

Elderly: No dosage modification is required in 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 listed in section 6.1, including methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) (see section 4.4).

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 142.6 mg sodium per 10 ml, equivalent to 7.1 % of the WHO recommended maximum daily intake for sodium.
The maximum daily dose of this product is equivalent to 57% 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 10 ml dose 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.

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

This medicine contains 1.1 mg benzyl alcohol (from Fennel flavour) per 10 ml dose. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

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 and 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:
Pre-clinical investigations have revealed alginate has no negative effect 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

None.

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

On ingestion the 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 mode of action of the product is physical and does not depend on absorption into the systemic circulation.

5.3. Preclinical Safety Data

No preclinical findings relevant to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Saccharin sodium
Fennel flavour
Erythrosine
Sodium hydroxide
Water

6.2. Incompatibilities

Not applicable.

6.3 Shelf life

Three years for 600ml pack size.

Two years for 100ml, 150ml, 200ml, 250ml, 300ml and 500ml pack sizes.

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 Winchester bottle with a polypropylene cap with a polyethylene tamper-evident band lined with expanded polyethylene wad containing 100, 150, 200, 250, 300, 500 and 600 ml.

6.6. Instruction for Use and Handling

No special instructions.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

PL 00063/0126

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/02/2009

10 DATE OF REVISION OF THE TEXT

09/01/2024