Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Liquid-Aniseed Flavour, Oral Suspension Each 10 ml contains: Sodium alginate 500 mg Sodium bicarbonate 267 mg Calcium carbonate 160 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients mg/10ml

Sodium alginate 500
Sodium bicarbonate 267
Calcium carbonate 160

Excipients with known effect:
Sodium 142.6mg (6.2 mmol) / 10ml. Total maximum daily dose (MDD) is 1140.8mg (49.6 mmol)
Benzyl alcohol 1.1mg /10ml, present in fennel flavour
Methyl parahydroxybenzoate (E218) 40mg /10ml
Propyl parahydroxybenzoate (E216) 6mg / 10ml

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

Pink, opaque suspension, with odour and flavour of aniseed.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

500 and 600 ml
For the management of gastric reflux, reflux oesophagitis, hiatus hernia, heartburn (including heartburn of pregnancy) and similar gastric distress.

150 and 300 ml
For the relief of stomach upset due to hyperacidity and heartburn (including heartburn of pregnancy).

4.2 Posology and method of administration

500 and600ml
Adultsand childrenover 12 years: 10-20 ml (two to four 5ml spoonfuls) after meals and before retiring.
Children 6 to 12years: 5-10 ml (one to two 5ml spoonfuls) after meals and before retiring.

150ml and300ml

Adults and children over 12years: 10-20 ml (two to four 5 ml spoonfuls) after meals and before retiring.
Children under12 years: Should be given only on medical advice. Not for use in children of 6 years or under.

Special PatientGroups:

Elderly: No dosage modification is required in this age group.
Hepaticimpairment: No modifications necessary.

RenalInsufficiency: Caution if highly restricted salt diet is necessary
(see section 4.4).

MethodofAdministration

For oral administration.

Duration of treatment

if symptoms do not improve after seven days, the clinical situation should be reviewed.

4.3 Contraindications

Hypersensitivity to Sodium alginate, Sodium bicarbonate, and calcium carbonate or to any of the excipients listed in 6.1, including the esters of hydroxybenzoates (parabens); methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) (see section 4.4).

4.4 Special warnings and precautions for use

As with all medicines, it is recommended to limit the treatment duration as much as possible. If symptoms do not improve after seven 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 up to 57.04% of the WHO recommended maximum daily intake for sodium for adults and up to 81% of the recommended maximum daily intake of sodium for children over 6 years.

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 10ml dose contains 160mg (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 1.1mg benzyl alcohol in each 10ml dose. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant, breastfeeding, or if you have 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').

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

Consult your doctor if you are over 40 years and have never suffered with heartburn and acid indigestion before.

4.5 Interaction with other medicinal products and other forms of interactions

Due to the presence of calcium and carbonates, a timeinterval of 2 hours should be considered between Gaviscon intake and theadministration of other medical products, especially tetracyclines,floroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates andestramustine. See also 4.4

4.6 Fertility, pregnancy and lactation

Pregnancy:
Clinical studies in more than 500 pregnant women as well as a large number 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:

Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction. 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 data do not suggest that Gaviscon has an effect on human fertility.

4.7 Effects on ability to drive and use machines

Gaviscon has no 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 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 Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

Symptoms

The patient may experience abdominal discomfort and may notice abdominal distension.

Management

In the event of an overdose symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drgus for peptic ulcer and gastro-oesophageal reflux disease (GORD); **ATC Code:** A02BX

On ingestion Gaviscon Liquid – Aniseed Flavour reacts 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 mode of action of Gaviscon Liquid – Aniseed Flavour 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 (E218)
Propyl parahydroxybenzoate (E216)
Saccharin sodium
Fennel flavour (benzyl alcohol)
Erythrosine soluble
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Amber glass bottles with a polypropylene cap with a polyethylene tamper-evident band with an expanded polyethylene wad containing 150, 300, 500 and 600 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/015/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 June 2001

Date of last renewal: 29 June 2006

10 DATE OF REVISION OF THE TEXT

April 2021