

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Liquid Peppermint Flavour, Oral Suspension

Sodium alginate	500 mg
Sodium bicarbonate	267 mg
Calcium carbonate	160 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains 500 mg sodium alginate, 267 mg sodium bicarbonate and 160 mg calcium carbonate.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension

Viscous, opaque, off-white to cream, peppermint flavoured suspension.

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.

100, 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

Posology

500 and 600 ml

Adults and children over 12 years: 10-20 ml (two to four 5 ml spoonfuls) after meals and before retiring.

Children 6-12 years: 5-10 ml (one to two 5 ml spoonfuls) after meals and before retiring.

100, 150 and 300 ml

Adults and children over 12 years: 10-20 ml (two to four 5 ml spoonfuls) after meals and before retiring.

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

Not for use in children of 6 years or under.

Duration of treatment

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

Special patient groups

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

Hepatic Impairment: No modifications necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary.

Method of administration

For oral administration

4.3 Contraindications

Hypersensitivity to Sodium alginate, Sodium bicarbonate, and Calcium carbonate or 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 seven days, consult your doctor.

All sizes

Each 10 ml dose has a sodium content of 141 mg (6.2 mmol). This should be taken into account when a highly restricted salt diet is recommended.

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216): May cause allergic reactions (possibly delayed).

Each 10ml dose contains 320 mg of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

100, 150 and 300 ml only

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 interaction

A time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, biphosphonates, 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.

Breastfeeding:

No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. Gaviscon can be used during breast-feeding and lactation.

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

Gaviscon has no or 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, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

In the event of overdosage symptomatic treatment should be given. The patient may notice abdominal distension.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease; **ATC Code:** A02BX

On ingestion Liquid Gaviscon 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 Liquid Gaviscon 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
Methylparahydroxybenzoate (E218)
Propylparahydroxybenzoate (E216)
Saccharin sodium
Peppermint oil
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two 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 100, 150, 300, 500 or 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 Limited
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/015/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 January 1996

Date of last renewal: 03 January 2006

10 DATE OF REVISION OF THE TEXT

June 2014