

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

This medicinal product contains 285.2 mg sodium (12.4 mmol) per 20 ml dose which is equivalent to 14.62% 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).

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

Each 20ml 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. Interactions 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. 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
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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 Centre, 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 overdose symptomatic treatment should be given.

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
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (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 content 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 and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PA 979/15/2.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 3rd January, 1996.
Date of last renewal: 3rd January, 2006.

10. DATE OF REVISION OF THE TEXT

January 2021