

# 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

<u>Active Substance</u>	<u>mg/10ml</u>
Sodium alginate	500.0
Sodium bicarbonate	267.0
Calcium carbonate	160.0

Each 10 ml dose contains 141 mg sodium and 46 mg Parahydroxybenzoate (E218 & E216).

For a full List of excipients, see 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

#### Posology

500 and 600 ml  
Adults and children over 12 years: 10-20 ml (two to four 5ml spoonfuls) after meals and before retiring.  
Children 6 to 12 years: 5-10 ml (one to two 5ml spoonfuls) after meals and before retiring.

150 ml 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.

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 (see section 4.4).

### **Method of Administration**

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**

If symptoms do not improve after seven days, consult your doctor.

### **All pack sizes**

Each 10 ml dose has a sodium content of 141 (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) which may cause allergic reactions (possibly delayed).

Each 10ml dose contains 160mg of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis, and recurrent calcium containing renal calculi.

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, bisphosphonates, 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 breastfeeding 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 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 IMB Pharmacovigilance, Earlfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.imb.ie](http://www.imb.ie); email: [imbpharmacovigilance@imb.ie](mailto: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 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  
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 Limited  
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**

February 2016