Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Liquid Sachets Oral Suspension Sodium alginate 500mg, Sodium bicarbonate 267mg, Calcium carbonate 160mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Gaviscon contains 500mg sodiumalginate, 267mg sodium bicarbonate and 160mg calcium carbonate per 10 ml dose.

Excipients: methyl parahydroxybenzoate (E218) 40 mg/10ml and propyl parahydroxybenzoate (E216) 6 mg/10 ml.
For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension in sachets.

An off-white suspension with the odour and flavour of peppermint.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion related to reflux, for example, following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis.

4.2 Posology and method of administration

Posology

Adults and children 12 years and over: One to two sachets after meals and at bedtime (up to four times a day).

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

Duration of treatment**:** If symptoms do not improve after seven days, the clinical situation should be reviewed.

Special Patient groups

Elderly: No dose modifications necessary for 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

4.3 Contraindications

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to sodium alginate, sodium bicarbonate, and calcium carbonate,or to any of the excipients listed ins ection 6.1, including methylparahydroxybenzoate (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, the clinical situation should be reviewed.
This medicinal product contains 285.2 mg sodium (12.4 mmol) per two sachet 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 to 57.04% 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, one sachet 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).
For children below 12 years. Please see section 4.2.

4.5 Interaction with other medicinal products and other forms of interactions

A time-interval of 2 hours should be considered between Gaviscon intake and the administration ofothermedicinalproducts,especiallytetracyclines,digoxine, fluoroquinolone,ironsalt, ketoconazole, neuroleptics, thyroid hormones, penicillamine, beta-blockers (atenolol, metoprolol,propanolol), glucocorticoid,chloroquine,estramustineandbisphosphonates (diphosphonates). See section 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 nomal formative norfeto/neonataltoxicity 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 effecton 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 rare:≤1/10,000.

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.
Itallows 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, Earlfort Terrace, IRL – Dublin 2; Tel: +353 1 676 4971; 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 classification: A02BX13. Other drugs for peptic ulcer and gastro- oesophageal reflux disease.
On ingestion the medicinal 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 in 3 minutes, effectively impeding gastro-oesophageal reflux for up to 4 hours. In severe cases the raft itself maybe refluxed into the oesophagus, in preference to the stomach contents, and exertademulcent effect.

5.2 Pharmacokinetic properties

The modeofaction of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No pre-clinical findings of any relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Saccharin sodium
Natural mint flavour
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 25°C and store in the original package. Do not freeze or refrigerate.

6.5 Nature and contents of container

A cardboard outer carton containing unit dose stick pack style sachets.

Pack sizes: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 36 and 48.

Not all pack sizes may be marketed.

The sachets are composed of polyester, aluminium and polyethylene.

Each sachet contains 10 ml of Gaviscon.

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 requirement.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/015/010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 2010
Date of last renewal: 12th November 2012

10 DATE OF REVISION OF THE TEXT

July 2022