

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Sachets Oral Powder Coolmint Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains sodium alginate 500 mg, sodium hydrogen carbonate 267 mg and calcium carbonate 160 mg.

Excipients: Aspartame E951.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral powder in sachet.

Cream coloured powder.

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 single dose containers after meals and at bedtime. The product is taken orally without water.

Children below 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).

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 in section 6.1.

4.4 Special warnings and precautions for use

The sodium content of a single dose container is 123 mg (5.3 mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment.

Each single dose container 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.

Due to its aspartame content this medicinal product should not be given to patients with phenylketonuria.

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

For children below 12 years, please see section 4.2.

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, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, estramustine and bisphosphonates (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 no malformative nor fetoneonatal 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.

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 rare: $\leq 1/10,000$

<u>System Organ Class</u>	<u>Frequency</u>	<u>Adverse Event</u>
Immune System Disorders	Very Rare	Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticarial
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: <http://www.hpra.ie/>; e-mail: medsafety@hpra.ie

4.9 Overdose

In the event of overdose 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 (GORD) ATC code: A02BX.

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 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 mechanism of action 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

Peppermint flavour
Macrogol 20,000
Macrogol 400
Aspartame (E951)
Citric acid anhydrous
Acesulfame potassium (E950)
Xylitol
Silicon dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Eighteen months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Pack sizes of 4, 6, 12, 16, 20, 24 or 32 unit dose sachets. The sachets are composed of printed polyester/polyethylene/aluminium foil/polyethylene.

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 Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/015/008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th July 2007

Date of last renewal: 13th July 2012

10 DATE OF REVISION OF THE TEXT

November 2014