

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Extra Liquid Sachets Peppermint Flavour Oral Suspension Sodium Alginate 500 mg/10 ml Sodium Bicarbonate 213 mg/10 ml Calcium Carbonate 325 mg/10 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml dose (sachet) contains sodium alginate 500 mg, sodium bicarbonate 213 mg and calcium carbonate 325 mg.

Excipients with known effects:

Methyl parahydroxybenzoate (E218) 40 mg
Propyl parahydroxybenzoate (E216) 6 mg
Sodium 127.88 mg

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension in sachet.

An off white suspension with the odour and flavour of peppermint

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

For oral administration.

Adults and children 12 years and over: 10-20 ml (1 to 2 sachets) after meals and at bedtime, up to four times per day.

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

Elderly: No dose modifications necessary for this age group.

4.3 Contraindications

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

This medicinal product contains 127.88 mg sodium per 10 ml / 1 sachet dose, equivalent to 6.39% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 51.15% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. 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 10 ml (sachet) contains 130 mg (3.25 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

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

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Prolonged use should be avoided.

As with other antacid products, taking Gaviscon Extra Liquid Sachets Peppermint Flavour Oral Suspension can mask the symptoms of other more serious, underlying medical conditions.

Gaviscon Extra Liquid Sachets Peppermint Flavour Oral Suspension should not be used in the following cases:

- Patients with server/impaired renal function/-insufficiency
- Patients with *hypophosphatemia*

There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

There is increased risk for hypernatremia in children with gastroenteritis or suspected renal insufficiency.

Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

4.5 Interaction with other medicinal products and other forms of interactions

Due to the presence of calcium and carbonates which act as an antacid, a time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially H₂-antihistaminics, tetracyclines, digoxin fluoroquinolone, iron salts, thyroid hormones, ketoconazole, neuroleptics, thyroxine, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, estramustine and diphosphonates. See also section 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy

A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/neonatal toxicity of the active substances.

Based on this and previous experience the medicinal product may be used during pregnancy if clinically needed.

Nevertheless, taking into account the presence of calcium carbonate it is recommended to limit the treatment duration as much as possible.

Breast-feeding

No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. This product can be used during breast-feeding if clinically needed.

Fertility

Pre-clinical animal 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

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events which have been associated with sodium alginate, sodium bicarbonate and calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ($\geq 1/10$); Common ($\geq 1/100$ and

<1/10); Uncommon ($\geq 1/1000$ and $< 1/100$); Rare ($\geq 1/10,000$ and $< 1/1000$); Very rare ($< 1/10,000$); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Very Rare	Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity reactions such as urticaria.
Metabolism and Nutritional Disorders	Not Known	Alkalosis ¹ , Hypercalcaemia ¹ , Milk-alkali Syndrome ¹
Respiratory, Thoracic and Mediastinal Disorders	Not known	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Very Rare	Abdominal pain, acid rebound, diarrhoea, nausea, vomiting
	Not Known	Constipation ¹
Skin and Subcutaneous Tissue Disorders	Very Rare	Rash Pruritic

Description of Selected Adverse Reactions

¹ Usually occurs following larger than recommended dosages.

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; +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

Symptoms

Some abdominal distension may be noticed.

Management

In the event of overdosage symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: A02BX, Other drugs for peptic ulcer and gastro-oesophageal reflux disease.

The medicinal product is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate.

On ingestion, the medicinal product reacts rapidly with gastric acid to form a protective barrier (raft) of alginic acid gel having a near neutral pH and which floats on the stomach contents. Effective impediment of gastro-oesophageal reflux may last up to 4 hours. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents and exert a demulcent effect.

Calcium carbonate neutralises gastric acid to provide fast relief from indigestion and heartburn. This effect is increased by the addition of sodium bicarbonate which also has a neutralising action. The total neutralising capacity of the product at the lowest dose of 10 ml is approximately 10 mEqH⁺. This effect has also been demonstrated in vivo via intragastric pH monitoring using a multi-electrode catheter in fasted healthy male and female participants to remove variability caused by postprandial buffering. In the study the primary endpoint was the percentage of time that intragastric pH ≥ 4 during the 30 minutes post-treatment period and the results recorded 50.8% of the time with Gaviscon Double Action versus 3.5 % with placebo (p=0.0051).

5.2 Pharmacokinetic properties

The mode 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

Carbomer 974P
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Saccharin sodium,
Peppermint 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 30°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

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

Pack sizes: 4, 12, 24, 48 and multipacks containing 48 (2x24) sachets.

Not all pack sizes may be marketed.

The sachets are composed of heat sealable laminate composed of polyester/aluminium foil/polyethylene/polyester/polyethylene.

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

PA0979/015/013

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 14th December 2012

Date of Last Renewal: 4th October 2017

10 DATE OF REVISION OF THE TEXT

September 2020