Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Oral Suspension Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml dose contains sodium alginate 500 mg and potassium hydrogen carbonate 100 mg.
Excipient(s) with known effect:
Methylparahydroxybenzoate (E218) (20 mg per 5 ml)
Propylparahydroxybenzoate (E216) (3 mg per 5 ml)
Sodium (57.85 mg per 5 ml)
Benzyl alcohol (0.525 mg per 5 ml) present in fennel flavour

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

Off-white, viscous suspension.

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: 5-10 ml after meals and at bedtime.

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 modification is required 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 use.

Shake well before use. Check that the cap seal is unbroken before first taking the product.

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, including methyl parahydroxybenzoate (E218) and propyl 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, the clinical situation should be reviewed.

Each 5 ml contains 1.0 mmol (40 mg) of calcium. 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): May cause allergic reactions (possibly delayed).

This medicinal product contains 2.5 mmol (57.85 mg) sodium per 5 ml dose, equivalent to 2.9% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 23.14% of the WHO recommended maximum daily intake for sodium. This is based on a 10 ml dose taken four times a day.
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) or when taking drugs which can increase plasma potassium levels.

This medicine contains 1.0 mmol (39.06 mg) potassium in each 5 ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains 0.525 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. Large amounts of benzyl alcohol can accumulate in the body and cause side effects (called 'metabolic acidosis'), which should be considered in pregnant or breast-feeding women, or patients with liver or kidney disease.

For children below 12 years, please see section 4.2.

4.5 Interaction with other medicinal products and other forms of interaction

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 tetracyclines, digoxin, fluoroquinolone, iron salts, thyroid hormones, ketoconazole, neuroleptics, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, estramustine and diphosphonates. See also section 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy:
Clinical studies in more than 500 pregnant women as well as a large number of data from post-marketing experience indicate no malformative no feto/neonatal toxicity of the active substances. Gaviscon can be used during pregnancy if clinically needed. See also section 4.4

Breastfeeding:
No known effect on breastfed infants. Gaviscon can be used during breast-feeding. See also section 4.4.

Fertility:
No known 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 or 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
Gastrointestinal disorders	Uncommon	Diarrhoea, nausea, vomiting
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 HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

Symptoms

Some abdominal discomfort may be experienced. The patient 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 (GORD).
ATC code: A02BX.

On ingestion the suspension 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 (up to 4 hours) 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 this product is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate
Carbomer 974P
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Saccharin sodium

Fennel flavour
Sodium hydroxide (for pH adjustment)
Purified water

Ingredients of fennel flavour:
Fennel anethol
Benzyl alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life: 2 years

Shelf-life after opening: 6 months.

6.4 Special precautions for storage

Do not refrigerate.

6.5 Nature and contents of container

Amber glass bottles with moulded polypropylene cap having a tamper evident strip and lined with an expanded polyethylene wad and containing 80, 100, 125, 140, 150, 180, 200, 250, 300, 400, 500, 560 or 600 ml suspension.

Or

Amber glass bottles with moulded polypropylene cap having a tamper evident strip and lined with an expanded polyethylene wad with either a measuring device (natural polypropylene) containing 5, 10, 15 and 20 ml graduations, or a measuring spoon (crystal polystyrene) containing 2.5 ml and 5 ml measure and containing 80, 100, 125, 140, 150, 180, 200, 250, 300, 400, 500, 560 or 600 ml suspension.
Not all pack sizes may be marketed. The carton and measuring device or spoon may not be made available in all markets/pack sizes.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th August 1998
Date of last renewal: 31st October 2011

10 DATE OF REVISION OF THE TEXT

February 2023