

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Peppermint Oral Suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml dose contains sodium alginate 1000mg and potassium hydrogen carbonate 200mg. 1 ml contains sodium alginate 100mg and potassium carbonate 20mg.

Each 10 ml dose is equivalent to two 5 ml measuring spoons.

For a 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, indigestion occurring due to the reflux of stomach contents, for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy or accompanying 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.

4.3 Contraindications

The 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 (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 10 ml dose has a sodium content of 106 mg (4.6 mmol) and a potassium content of 78 mg (2.0 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 or when taking drugs which can increase plasma potassium levels.

Each 10 ml contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

This medicinal product contains Methyl hydroxybenzoate and Propyl hydroxybenzoate, 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 interaction

None known.

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.

Breastfeeding:

No known effect on breastfed infants. Gaviscon can be used during breast-feeding.

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 of 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.

<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 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, 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 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 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 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
Peppermint flavour
Sodium hydroxide for pH adjustment
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Shelf-life after first opening container: 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. The bottles are enclosed in a cardboard outer containing either a measuring device (natural

polypropylene) containing 5, 10, 15 and 20 ml graduations or a clear injection moulded crystal polystyrene measuring spoon with one bowl containing 2.5 ml and 5 ml measure. The pack sizes are 80, 100, 125, 140, 150, 180, 200, 250, 300, 400, 500, 560 or 600 ml suspension.

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

PA0979/011/007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 March 2004

Date of last renewal: 15 March 2006

10 DATE OF REVISION OF THE TEXT

March 2015