

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Peppermint Oral Suspension Sachets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml dose contains sodium alginate 500 mg and potassium hydrogen carbonate 100 mg. 1 ml contains sodium alginate 100 mg and potassium hydrogen carbonate 20 mg.

Excipients: methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216)

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

Off-white viscous suspension in sachets.

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.

Any unused solution should be discarded.

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 (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 dose has a sodium content of 53 mg (2.3 mmol) and a potassium content of 39 mg (1.0 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 5 ml contains 100 mg (1.0 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 amount of data from post-marketing experience indicate no malformative nor feto/neonatal toxicity of the active substances. Gaviscon can be used during pregnancy.

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 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
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.

6.4 Special precautions for storage

Do not refrigerate.

6.5 Nature and contents of container

A cardboard outer carton containing unit dose stick pack style sachets and a clear injection moulded crystal polystyrene measuring spoon with one bowl containing 2.5ml and 5ml measure. The pack sizes are 4, 10, 12, 20, 24 or 48. Not all

pack sizes may be marketed.

The spoon may not be made available in all market/pack sizes. The sachets are comprised of polyester, aluminium and polyethylene.

A single sachet, or dual sachets, enclosed in an outer cardboard carton, are also available. Each sachet contains either 5 or 10 ml of medicinal product.

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

PA 0979/011/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 March 2004

Date of last renewal: 27 June 2007

10 DATE OF REVISION OF THE TEXT

March 2015