

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Peppermint 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.

Excipients with known effect:

Methylparahydroxybenzoate (E218) (20 mg / 5 ml)

Propylparahydroxybenzoate (E216) (3 mg / 5 ml)

Sodium (57.85 mg / 5 ml)

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

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 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.

This medicinal product contains 2.5 mmol (57.85 mg) of sodium per 5 ml, 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 per 5 ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

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

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 or fetoneonatal 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).

<b><u>System Organ Class</u></b>	<b><u>Frequency</u></b>	<b><u>Adverse Event</u></b>
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 HPRC Pharmacovigilance. Website: [www.hpra.ie](http://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 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 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**

PA0979/011/007

## **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**

February 2023