# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Peppermint Flavour

Oral Suspension.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml dose contains sodium alginate 1000 mg and potassium hydrogen carbonate 200 mg. 1 ml contains sodium alginate 100 mg and potassium hydrogen carbonate 20.0 mg.

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

Excipient(s) with known effect:
Methyl parahydroxybenzoate E218
Propyl parahydroxybenzoate E216

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 resulting from the reflux of acid, bile and pepsin into the oesophagus 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, accompanying reflux oesophagitis, including symptoms of laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throats and cough. It can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

## 4.2 Posology and method of administration

Adults and children 12 years and over: 5-10 ml after meals and at bedtime (one to two 5 ml measuring spoons).

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

Elderly: No dose modification is required for this age group.

Hepatic Impairment: No dose modification necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary (see section 4.4).

## 4.3 Contrindications

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 7 days, the clinical situation should be reviewed.

This medicinal product contains 57.85 mg 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 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).

Potassium: 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.

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).

## 4.5 Interaction with other medicinal products and other forms of interaction

A time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

## 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 foeto/neonatal toxicity of the active substances. Gaviscon can be used during pregnancy, if clinically needed.

**Breast feeding:**
No known effect on breast fed 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

Not relevant.

## 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

**Symptoms**

Symptoms are likely to be minor; some abdominal discomfort may be experienced.

**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 rapidly form a raft of alginic acid gel having a near-neutral pH which floats on the stomach contents quickly and effectively impeding gastro-oesophageal reflux for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases the raft itself may be refluxed into the oesophagus in preference to the stomach contents and exert a demulcent effect. In addition in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within its structure, further protecting the oesophagus from these gastric components.

### 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.

## 6.1 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

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. 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. 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

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom.

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0612.

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/10/2024

## 10 DATE OF REVISION OF THE TEXT

21/10/2024