SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Aniseed Suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances	**mg/10ml**
Sodium alginate	1000.0
Potassium bicarbonate	200.0

Excipient(s) with known effect:

Methyl parahydroxybenzoate E218 (20 mg/ 5 ml)

Propyl parahydroxybenzoate E216 (3 mg/ 5 ml).

Sodium (57.85 mg (2.515 mmol)/ 5 ml)

Potassium (39.06 mg/ 5 ml)

Benzyl alcohol* (0.525 mg/ 5 ml)

*present in the fennel flavour

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
An 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. 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

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

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients, or 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.

Warning related to Excipients:

Sodium: 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 1mmol (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.

Calcium: Each 10 ml contains 200 mg (2 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Methyl and propyl parahydroxybenzoate: Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216): May cause allergic reactions (possibly delayed).

Benzyl alcohol: This medicine contains 0.525 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").
Ask your doctor or pharmacist for advice if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

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

None

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 classification: A02E A01 Anti-regurgitant

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 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 it structure, further protecting the oesophagus from these gastric components.

5.2 Pharmacokinetic properties

The mode of action of Gaviscon Advance Aniseed Suspension 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

Methyl parahydroxybenzoate

Propyl parahydroxybenzoate

Saccharin sodium

Fennel flavour

Sodium hydroxide

Potassium

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years

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, 500, 560 or 600 ml suspension.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited

Dansom Lane

Hull

HU8 7DS

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0108

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 April 2002

10 DATE OF REVISION OF THE TEXT

13/09/2024