Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product Name: Gaviscon Advance Aniseed Liquid
Dosage: Suspension
strength: Each 5,0 ml contains Sodium Alginate 500,0 mg
Safety and Clinical update: 03 June 2025

1.3.1.1.1 APPROVED PROFESSIONAL INFORMATION
SCHEDULING STATUS:

S0

1. NAME OF THE MEDICINE

GAVISCON@ ADVANCE ANISEED

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5ml contains Sodium Alginate 500 mg in a thickened base of sodium bicarbonate, calcium carbonate.

Preservatives:

Methylhydroxybenzoate 20,000 mg per 5 ml

Propylhydroxybenzoate 3,000 mg per 5 ml

Sugar free

Contains sweetener: Saccharin Sodium 5,000 mg per 5 ml

3. PHARMACEUTICAL FORM:

Suspension

An off-white to pale brown suspension with an odour and flavour of fennel (aniseed).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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GAVISCON@ ADVANCE ANISEED is indicated for the following conditions: Gastric reflux, reflux oesophagitis, heartburn, including heartburn of pregnancy, hiatus hernia, flatulence associated with gastric reflux and all cases of epigastric and retro-sternal distress, where the underlying cause is gastric reflux.

4.2 Posology and method of administration Posology

SHAKE WELL BEFORE USE.

Adults and children over 12 years:	5-10 ml after meals and at bedtime.
Children under 12 years:	Not recommended.

4.3 Contraindications:

GAVISCON@ ADVANCE ANISEED 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 warning and precautions to use

If symptoms do not improve after 7 days, the clinical situation should be reviewed.

1.3.1.1.1 APPROVED PROFESSIONAL INFORMATION

Each 5 ml dose of GAVISCON@ ADVANCE ANISEED contains 53mg (2.3 mmol) of sodium and 39mg (1.0 mmol) potassium. As congestive cardiac failure may result from excessive sodium absorption, GAVISCON@ ADVANCE ANISEED should be administered with caution to patients on a highly restricted salt diet.

Hypercalcaemia/alkalosis can occur following the regular use of calcium carbonate.

Administration of potassium may cause hyperkalaemia in patients with renal failure.

Each 5 ml contains 200 mg (1.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

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

GAVISCON@ ADVANCE ANISEED contains 0.525 mg benzyl alcohol in each 5 ml.

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”).

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).

Paediatric population

In Children under 12 years GAVISCON@ ADVANCE ANISEED should be given only on medical advice.

4.5 Interactions with other medicinal products and other forms of interaction

Large doses of antacids can interfere with the absorption of some medicines.

A time-interval of 2 hours should be considered between GAVISCON@ ADVANCE ANISEED 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

This medicine can be used as directed during pregnancy and lactation.

Pregnancy:

1.3.1.1.1 APPROVED PROFESSIONAL INFORMATION

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@ ADVANCE ANISEED can be used during pregnancy, if clinically needed.

Breast feeding:

No known effect on breast fed infants. GAVISCON@ ADVANCE ANISEED 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).

1.3.1.1.1 APPROVED PROFESSIONAL INFORMATION

System Organ Class	Frequency	Adverse Event
Gastrointestinal Disorders	Uncommon	Stomach cramps, flatulence, constipation 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 **(Heading and text added in line with PI guideline)**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Contact details for the reporting of side effects: 0861 11 1100

4.9 Overdose

Very large doses may produce a feeling of abdominal distension. Treatment of overdosage is symptomatic and supportive.

5. PHARMALOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: A02BX13

A 11.10 Medicines acting on gastro-intestinal tract. Special combinations.

On ingestion sodium alginate reacts with saliva and gastric acid to produce a viscous gel which floats on the stomach contents effectively impending gastro-oesophageal for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases, the gel itself may be refluxed into the oesophagus where it helps protect the mucosa. 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 flavour Oral Suspension is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

There are no preclinical findings of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate

Carbomer

Methyl parahydroxybenzoate (E218) (preservatives)

Propyl parahydroxybenzoate (E216) (preservatives)

Saccharin sodium (sweetener)

Fennel flavour

Sodium hydroxide

Potassium hydrogen carbonate

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years

6.4 special precautions for storage

Store in a well closed container below 30 ^{0}C. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Amber glass bottles containing 150 ml, 180 ml, 200 ml, 500 ml or 600 ml.

6.6 Special precautions for disposal

Not applicable

7. HOLDER OF CERTIFICATE OF REGISTRATION

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road,

Elandsfontein

1601

Customer Care line: 0861 11 1100

8. REGISTRATION NUMBER:

32/11.10/0207

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

1.3.1.1.1 APPROVED PROFESSIONAL INFORMATION
6 August 1999

10. DATE OF REVISION OF THE TEXT

20 January 2026