Gaviscon Advance Aniseed Liquid
Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Updated Package Insert

SCHEDULING STATUS:

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PROPRIETARY NAME (AND DOSAGE FORM):

GAVISCON® ADVANCE ANISEED (Suspension)

COMPOSITION:

Each 5ml contains Sodium Alginate 500mg in a thickened base.

Preservatives:

Methylhydroxybenzoate	0.4% m/v
Propylhydroxybenzoate	0.06% m/v

PHARMACOLOGICAL CLASSIFICATION:

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

PHARMACOLOGICAL ACTION:

On ingestion sodium alginate reacts with saliva and gastric acid to produce a viscous gel which floats on the stomach contents suppressing gastric reflux. In severe cases, the gel itself may be refluxed into the oesophagus where it helps protect the mucosa.

INDICATIONS:

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.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients.

INTERACTIONS:

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

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PREGNANCY AND LACTATION:

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

DOSAGE AND DIRECTIONS FOR USE:

SHAKE WELL BEFORE USE.

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

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Uncommon:

- **Gastrointestinal disorders:** Stomach cramps, flatulence, constipation

Very rare (<1/10 000)

- **Hypersensitivity:** Urticaria, bronchospasm

Respiratory Disorders: Bronchospasm

- **Musculo-skeletal disorders:** Abdominal distension and abdominal cramps
- **Gastro intestinal disorders:** Nausea, vomiting and diarrhoea

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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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

and supportive.

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IDENTIFICATION:

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

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store in a well closed container below 30°C. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

32/11.10/0207

NAME AND BUSINESS ADDRESS OF APPLICANT:

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DATE OF PUBLICATIONS OF THIS PACKAGE INSERT:

6 August 1999