Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product: Gaviscon Liquid Peppermint 29/11.10/0641
Dosage: Suspension
Strength: Each 10 ml contains Sodium Alginate 500 mg
PI Safety Update: 10 April 2025
PI/PIL Approval: 26 August 2025
1.3.1.1.1 APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

GAVISCON LIQUID PEPPERMINT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 10 ml suspension contains sodium alginate 500 mg in a thickened base of sodium bicarbonate, calcium carbonate.

Preservatives:

Methylhydroxybenzoate 40,000 mg per 10 ml

Propylhydroxybenzoate 6,000 mg per 10 ml

Sugar free

Contains sweetener: Saccharin Sodium 10,000 mg per 10 ml

3. PHARMACEUTICAL FORM:

Suspension

Opaque, off-white to cream suspension with a flavour of peppermint

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

GAVISCON LIQUID PEPPERMINT 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: 10 - 20 ml after meals and at bedtime.

Children under 12 years: 10 ml after meals and at bedtime.

Children under 2 years: Although GAVISCON LIQUID PEPPERMINT are not normally recommended for children under the age of two, where the physician considers its use necessary, a dose of 5 ml should not be exceeded.

Method of administration

For oral use.

4.3 Contraindications:

GAVISCON LIQUID PEPPERMINT 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 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.

Each 10 ml dose GAVISCON LIQUID PEPPERMINT contains 145 mg (6,3 mmol) of sodium. As congestive cardiac failure may result from excessive sodium absorption, GAVISCON LIQUID PEPPERMINT should be administered with caution to patients on a highly restricted salt diet.

Sodium bicarbonate should be administered with caution in patients with cognitive heart failure, renal impairment, cirrhosis of the liver, hypertension and to patients receiving corticosteroids, patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.
Hypercalcaemia/alkalosis can occur following the regular use of calcium carbonate.

Elderly: No dosage modification is required in this age group.

Hepatic Impairment: No dose modification necessary.

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

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Paediatric population

In children under 12 years GAVISCON LIQUID PEPPERMINT should be given only on medical advice.

4.5 Interactions with other medicinal products and other forms of interaction:

Large doses of GAVISCON LIQUID PEPPERMINT may affect the rate and/or the extent of absorption of other oral medicines.

A time-interval of 2 hours should be considered between GAVISCON LIQUID PEPPERMINT intake and the administration of other medicinal products, especially tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicillamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine and biphosphonates (diphosphonates) and estramustine. (see also 4.4).

4.6 Fertility, Pregnancy and Lactation:

Problems with taking GAVISCON LIQUID PEPPERMINT during lactation have not been documented.

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 feto/ neonatal toxicity of the active substances. GAVISCON LIQUID PEPPERMINT can be used during pregnancy, if clinically needed.

Breastfeeding

No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. GAVISCON LIQUID PEPPERMINT can be used during breast-feeding.

Fertility

GAVISCON LIQUID PEPPERMINT has no negative effect in parental or offspring fertility or reproduction. Clinical data do not suggest that GAVISCON LIQUID PEPPERMINT has 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 to < 1/10; uncommon: ≥ 1/1,000 to < 1/100; rare: ≥ 1/10,000 to < 1/1,000; very rare: < 1/10,000; Not known: cannot be estimated from the available data.

Side effects:

System Organ Class	Frequency	Adverse Event
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.
Gastrointestinal disorders	Not known/uncommon	Stomach cramps, flatulence.

Reporting of suspected adverse reactions

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. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodyinamic properties

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

Pharmacotherapeutic group: Alimentary tract and metabolism; Drugs for acid related disorders; Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD); **ATC Code: A02BX13.**

On ingestion GAVISCON LIQUID PEPPERMINT reacts with saliva and gastric acid to produce a viscous gel, which floats on the stomach contents quickly and effectively impeding gastro-oesophageal reflux, for up to 4 hours. In severe cases, the gel itself may be refluxed into the oesophagus where it helps protect the mucosa.

5.2 Pharmacokinetic Properties

The mode of action of the product is physical and does not depend on absorption into the systematic circulation.

5.3 Preclinical Safety Data

No preclinical findings relevant to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer

Methyl parahydroxybenzoate (preservatives)

Propyl parahydroxybenzoate (preservatives)

Saccharin sodium (sweetener)

Peppermint oil

Sodium hydroxide

Water

6.2 **Incompatibilities**

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25 °C. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and content of container

Amber glass bottles containing 150 ml, 300 ml or 600 ml.

6.6 Special precautions for disposal and other handling

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8 Jet Park Road,

Elandsfontein 1406

Customer Care line: 0861 11 1100

8. REGISTRATION NUMBER:

29/11.10/0641

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

07 July 2006

10. DATE OF REVISION OF THE TEXT

26 August 2025

*On the printed version, pack sizes may be limited to those actually marketed.

REFERENCES

1	Gaviscon Peppermint Liquid Relief-UK-SmPC-09-01-2024