

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
PIL Safety Update: 10 April 2025
PI/PIL approval: 26 August 2025

1.3.2.1 Approved Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

NAME OF THE MEDICINE

GAVISCON LIQUID PEPPERMINT

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

Read all of this entire leaflet carefully because it contains important information for you.

GAVISCON LIQUID PEPPERMINT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GAVISCON LIQUID PEPPERMINT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GAVISCON LIQUID PEPPERMINT with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What GAVISCON LIQUID PEPPERMINT is and what it is used for
2. What you need to know before you take GAVISCON LIQUID PEPPERMINT
3. How to take GAVISCON LIQUID PEPPERMINT
4. Possible side effects
5. How to store GAVISCON LIQUID PEPPERMINT

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6. Contents of the pack and other information

1. What GAVISCON LIQUID PEPPERMINT is and what it is used for

GAVISCON LIQUID PEPPERMINT relieves symptoms of heartburn, including heartburn of pregnancy, and flatulence. It works by reacting with saliva and stomach acid to make a viscous gel that floats on top of the stomach contents. The 'raft-like' gel helps stop the reflux of the stomach contents and relieves heartburn.

2. What you need to know before you take GAVISCON LIQUID PEPPERMINT

Do not take GAVISCON LIQUID PEPPERMINT:

- If you are hypersensitive (allergic) to sodium alginate or any of the other ingredients including methyl parahydroxybenzoate (E218) and parahydroxybenzoate (E216)

Warning and precautions

Take special care with GAVISCON LIQUID PEPPERMINT if you have any of the following:

- Kidney disease
- Electrolyte imbalances (e.g. low calcium levels)
- Cirrhosis of the liver
- Heart failure
- High blood pressure
- Too much calcium in the blood
- Low levels of acid in the stomach
- On restricted salt diet

Children and adolescents:

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

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Other medicines and GAVISCON LIQUID PEPPERMINT

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Large doses of GAVISCON LIQUID PEPPERMINT may affect the absorption of other oral medicines.

Leave 2-hour interval between GAVISCON LIQUID PEPPERMINT intake and administration of any of the following medicines:

- Tetracyclines (antibiotic for bacteria infections)
- Medicines for heart problems such as digoxin, atenolol, metoprolol, propranolol
- Fluoroquinolone (medicine for respiratory infection)
- Iron salt
- Ketoconazole (medicine for fungal infections like yeast infection or athlete's foot)
- Neuroleptics (medicine for mental disorders)
- Thyroid hormones
- Penicillamine (medicine for kidneys problems)
- Glucocorticoid (medicine for allergies, inflammation, asthma)
- Chloroquine (anti-malarial medicine)
- And biphosphonates (for bone fractures)
- Estramustine (medicine for prostate cancer)

GAVISCON LIQUID PEPPERMINT with food and drink

GAVISCON LIQUID PEPPERMINT is usually taken after meals and at bedtime.

Pregnancy, breast-feeding and fertility

Pregnancy and breast-feeding

GAVISCON LIQUID PEPPERMINT is used for heartburn of pregnancy.

Problems with taking GAVISCON LIQUID PEPPERMINT while breast-feeding have not been reported.

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If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking GAVISCON LIQUID PEPPERMINT.

Driving and using machines:

GAVISCON LIQUID PEPPERMINT is not expected to interfere with driving or the ability to operate tools or machines.

It is not always possible to predict to what extent GAVISCON LIQUID PEPPERMINT may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GAVISCON LIQUID PEPPERMINT affects them.

GAVISCON LIQUID PEPPERMINT contains calcium carbonate

High blood levels of calcium can occur following the regular use of calcium carbonate.

3. HOW TO TAKE GAVISCON LIQUID PEPPERMINT

Do not share GAVISCON PEPPERMINT prescribed for you with any other person

SHAKE WELL BEFORE USE.

Always take GAVISCON LIQUID PEPPERMINT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

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.

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Children under 2 years: Not normally recommended for children under the age of two years.

Give only on advice of the doctor. Do not give more than 5 ml after meals and at bedtime.

If you have the impression that the effect of GAVISCON LIQUID PEPPERMINT is too strong or too weak, talk to your doctor or pharmacist.

If you take more GAVISCON LIQUID PEPPERMINT than you should:

Very large doses may cause bloating. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take GAVISCON LIQUID PEPPERMINT:

- If you miss a dose of this medicine and you are taking it regularly, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

GAVISCON LIQUID PEPPERMINT can have side effects.

Not all side effects reported for GAVISCON LIQUID PEPPERMINT are included in this leaflet. Should your general health worsen while taking GAVISCON LIQUID PEPPERMINT, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking / using GAVISCON LIQUID PEPPERMINT and tell your doctor immediately or go to the casualty department at your nearest hospital:

Anaphylaxis – severe allergic reaction with signs such as breathing difficulties, skin rash, swelling on the face or mouth.

Rash or itching

These are all very serious side effects. If you have them, you may have had a serious reaction to GAVISCON LIQUID PEPPERMINT. You may need urgent medical attention or hospitalisation.

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Tell your doctor if you notice any of the following:

- Stomach cramps
- Flatulence

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of GAVISCON LIQUID PEPPERMINT.

5. How to store GAVISCON LIQUID PEPPERMINT

Store GAVISCON LIQUID PEPPERMINT in a dry and cool place (below 25 °C).

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GAVISCON LIQUID PEPPERMINT contains:

Each 10 ml of GAVISCON LIQUID PEPPERMINT contains sodium alginate 500 mg.

The other ingredients are sodium bicarbonate, calcium carbonate carbomer, sodium saccharin, peppermint oil, sodium hydroxide and water.

Preservatives: Methylhydroxybenzoate 40,000 mg per 10 ml and propylhydroxybenzoate 6,000 mg per 10 ml.

Contains sweetener:

Saccharin Sodium 10,000 mg per 10 ml

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What GAVISCON LIQUID PEPPERMINT looks like and contents of the pack

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

GAVISCON LIQUID PEPPERMINT is available in amber glass bottles containing 150 ml, 300 ml or 600 ml.

Holder of Certificate of Registration

©Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road,

Elandsfontein 1406

Customer care line: 0861 11 1100

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REGISTRATION NUMBER

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Access to the corresponding Professional Information

Please go to the link to access to the corresponding PI:

<https://cpdcentre.co.za/rb-product-inserts/>

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