

LEAFLET TEXT

Package leaflet: Information for the user

Gaviscon Liquid Aniseed Flavour Oral Suspension

Sodium alginate 500mg/10ml, Sodium bicarbonate 267mg/10ml, Calcium carbonate 160mg/10ml

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. However you still need to take this medicine carefully to get the best results from it.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What is Gaviscon Liquid and what is it used for?
2. What you need to know before taking Gaviscon Liquid
3. How to take Gaviscon Liquid
4. Possible side-effects
5. How to store Gaviscon Liquid
6. Contents of the pack and other information.

1. What Gaviscon Liquid is and what it is used for?

Gaviscon Liquid belongs to a group of medicines called “reflux suppressants”. This product forms a protective layer that floats on top of the stomach contents. This layer prevents reflux and keeps the stomach contents away from the lining of the food pipe to relieve the symptoms of heartburn and acid indigestion.

This medicine is used for the treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis.

2. What you need to know before taking Gaviscon Liquid

Do not take Gaviscon Liquid:

- If you know you are allergic (hypersensitive) to any of the ingredients in this product (see “further information” for a full list of ingredients).

Take special care with Gaviscon Liquid:

This medicine contains 142.6 mg sodium (main component in cooking/table salt) in each 10ml. This is equivalent to 7.1% of the recommended maximum daily dietary intake of sodium for an adult.

The maximum daily dose of this product is equivalent up to 57.04% of the WHO recommended maximum daily intake for sodium for adults and up to 81% of the recommended maximum daily intake of sodium for children over 6 years.

This medicine is considered high in sodium and if you have been advised to follow a diet restricted in any of these, please consult your doctor. Please talk to your doctor regarding these salt contents if you suffer or have suffered from significant kidney or heart disease, as certain salts could interfere with these diseases.

This medicine contains 1.6 mmol of calcium per 10ml dose.

This medicine contains 1.1 mg benzyl alcohol in each 10 ml. Benzyl alcohol can cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or 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').

Also contains methyl (E218) & propyl (E216) parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Consult your doctor if you are over 40 years and have never suffered with heartburn and acid indigestion before.

If symptoms persist after 7 days consult your doctor.

Other medicines and Gaviscon Liquid

Do not take this medicine within two hours of taking other medicines by mouth as it can interfere with the action of some other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. A time interval of 2 hours should be considered between Gaviscon intake and administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates and estramustine.

Pregnancy and breast-feeding:

You can take this product if you are pregnant or breast-feeding. As with all medicines, the treatment duration should be limited as much as possible.

Driving and using machines:

This medicine has no influence on the ability to drive and use machines.

3. How to take Gaviscon Liquid

For oral administration.

Check that the cap seal is unbroken before first using this product. Shake well before use.

Adults and children 12 years and over: 10-20ml (two to four 5ml spoonfuls) after meals and at bedtime.

Children under 12 years old: Should only be taken on medical advice.

Not for use in children of 6 years or under.

If you forget a dose it is not necessary to double the dose next time, just carry on taking as before.

If you take more Gaviscon Liquid than you should

If you take too much of this product you may feel bloated and experience some abdominal discomfort. Consult your doctor or pharmacist if this doesn't go away.

4. Possible side effects

Very rarely (less than 1 in 10,000 patients) there is a chance of an allergic reaction to the ingredients. Symptoms of this may include skin rash, itching, difficulty breathing, dizziness or swelling of the face, lips, tongue or throat. If you experience these or any other side effects stop taking the product and consult your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gaviscon Liquid

Keep this medicine out of the sight and reach of children.

Do not use Gaviscon Liquid after the expiry date (EXP: month/year) shown.

Do not store above 30°C

Do not refrigerate.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Gaviscon Liquid contains

Each 10 ml of oral suspension contains 500 mg sodium alginate and 267 mg sodium bicarbonate and 160 mg calcium carbonate as the active ingredients.

The other ingredients are carbomer, methyl (E218) and propyl (E216) parahydroxybenzoates, sodium saccharin, sodium hydroxide, aniseed flavour derived from fennel (benzyl alcohol), erythrosine and purified water.

This product does not contain sugar or gluten.

What Gaviscon Liquid looks like and contents of the pack

Gaviscon Liquid is an opaque, pink oral suspension with the odour of fennel.

Gaviscon Liquid is available in bottles of 150 ml, 300 ml or 600 ml.

Manufacturers: Reckitt Benckiser Healthcare (UK) Ltd., Hull HU8 7DS, UK and RB NL Brands BV. Schiphol Blvd 207, 1118 BH Schiphol, NL.

PA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24.

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