

LEAFLET TEXT

Package leaflet: information for the user

Gaviscon Extra Oral Suspension
Sodium alginate 500mg
Sodium bicarbonate 213mg
Calcium carbonate 325mg

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. 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 Extra Oral Suspension and what is it used for?
2. What you need to know before you take Gaviscon Extra Oral Suspension
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4. Possible side-effects
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1. What is Gaviscon Extra Oral Suspension and what is it used for?

Gaviscon Extra Oral Suspension is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate which work in two ways:

1. Neutralising excess stomach acid to relieve the pain and discomfort
2. Forming a protective barrier over the stomach contents to soothe the burning pain in your chest which may last for up to 4 hours.

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

2. What you need to know before you take Gaviscon Extra Oral Suspension

Do not take Gaviscon Extra Oral Suspension:

If you know you are allergic to any of the ingredients of this medicine (listed in section 6)

Talk to your doctor or pharmacist before using Gaviscon Extra Oral Suspension if you:

- Suffer or have suffered from significant kidney or heart disease, as certain salts could interfere with these diseases
- Have severe kidney problems

- Have electrolyte disturbance causing low level of phosphate in the blood (hypophosphatemia)
- Know you have reduced amounts of gastric acid in your stomach, as this product may be less effective

As with other antacid products, taking Gaviscon Extra Oral Suspension can mask the symptoms of other more serious underlying medical conditions. If symptoms persist after 7 days consult your doctor.

Children

Do not give this medicine to a child under 12 years of age except on the advice of a doctor. There is a risk of increased levels of sodium in the blood (hyponatremia) in children who have kidney problems or who have an inflamed stomach or bowel (gastroenteritis)

Other medicines and Gaviscon Extra Oral Suspension

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 obtained without prescription.

Pregnancy, breast-feeding and fertility:

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

Important information about some of the ingredients of Gaviscon Extra Oral Suspension:

This product contains methyl (E218) and propyl (E216) para-hydroxybenzoates which may cause allergic reactions (possibly delayed). It also contains 260 mg (6.50 mmol) calcium per 20 ml dose. Speak to a doctor before taking this medicine if you have kidney stones or high levels of calcium in your blood.

The maximum recommended daily dose of this medicinal product contains 1,023 mg sodium (found in table salt). This is equivalent to 51.15% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Gaviscon Extra Oral Suspension on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How to take Gaviscon Extra Oral Suspension

For oral administration. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Shake well before use.

Adults including the elderly and children 12 years and over: 10-20ml after meals and at bedtime, up to four times a day.

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

If you take more Gaviscon Extra Oral Suspension than you should:

If you take too much of this product it is unlikely to cause you any harm. However, you may feel bloated. Consult your doctor if this doesn't go away.

If you forget to take Gaviscon Extra Oral suspension:

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

4. Possible side effects

Like all medicines, Gaviscon Extra Oral Suspension can cause side effects, although not everybody gets them. If you experience these side effects stop taking the product and consult your doctor immediately. Very rarely (less than 1 in 10,000) chance of an allergic reaction from the ingredients. Symptoms of this may include abdominal pain, diarrhoea, nausea, vomiting, skin rash, itching, dizziness, swelling of the face, lips, tongue or throat and difficulty in breathing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can report side effects directly via HPRA

Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 16762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

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

5. How to store Gaviscon Extra Oral Suspension

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

Do not use this product after the expiry date which is stated on the bottle after EXP (month/year). The expiry date refers to the last date of that month.

Do not store above 30°C.

Do not refrigerate or freeze.

Use within 6 months of opening. Check the cap seal is unbroken before first using this product.

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 Extra Oral Suspension contains:

The active substances in each 10 ml contains 500 mg sodium alginate, 213 mg sodium bicarbonate and 325 mg calcium carbonate.

The other ingredients are carbomer, methyl (E218) and propyl (E216) parahydroxybenzoates, sodium saccharin, peppermint flavour, sodium hydroxide and water.

This product does not contain sugar or gluten.

What Gaviscon Extra Oral Suspension looks like and contents of the pack

Gaviscon Extra Oral Suspension is an off-white to cream suspension with the odour and flavour of peppermint.

Gaviscon Extra Oral Suspension is available in bottles of 150ml, 300ml and 600ml bottles. Not all sizes may be marketed.

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

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

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Product Queries: Please call 01-6305429