

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 your symptoms worsen or do not improve 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.
3. How to take Gaviscon Extra Oral Suspension.
4. Possible side-effects.
5. How to store Gaviscon Extra Oral Suspension.
6. Contents of the pack and further information.

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 and 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.

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 product 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) parahydroxybenzoates which may cause allergic reactions (possibly delayed). This medicinal product It also contains 127.35mg (5.53 mmol) sodium per dose. To be taken into consideration by patients on a controlled sodium diet. It also contains 130 mg (3.25 mmol) calcium per dose. Speak to a doctor before taking this medicine if you have kidney stones or high levels of calcium in your blood

3. **HOW TO TAKE GAVISCON EXTRA ORAL SUSPENSION**

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 before 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 rare (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 also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. **HOW TO STORE GAVISCON EXTRA ORAL SUSPENSION**

Keep out of the reach and sight 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 day 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 FURTHER INFORMATION**

What Gaviscon Extra Oral Suspension contains:

The active substances in each 10ml 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, 200ml 300ml, and 600ml bottles. Not all sizes may be marketed.

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

Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd., Hull, HU8 7DS, UK

This leaflet was last approved in March 2016

Product Queries: Please call 01-6305429