

Package Leaflet Information for the User

GAVISCON EXTRA LIQUID SACHETS

PEPPERMINT FLAVOUR

500mg/213mg/325mg

Oral Suspension in sachet

Sodium alginate / Sodium bicarbonate / Calcium carbonate

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 are Gaviscon Extra Liquid Sachets Peppermint Flavour and what are they used for?
2. What you need to know before you take Gaviscon Extra Liquid Sachets Peppermint Flavour
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1. WHAT ARE GAVISCON EXTRA LIQUID SACHETS PEPPERMINT FLAVOUR AND WHAT ARE THEY USED FOR?

Gaviscon Extra Liquid Sachets Peppermint Flavour 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 LIQUID SACHETS PEPPERMINT FLAVOUR

Do not take Gaviscon Extra Liquid Sachets Peppermint Flavour 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 Liquid Sachets Peppermint Flavour if you

- have **severe kidney problems**
- have electrolyte disturbance causing **low level of phosphate** in the blood (hypophosphatemia).
- suffer or have suffered from significant **kidney or heart disease**, as certain salts could interfere with these diseases (talk to your doctor regarding the salt content).
- know you have **reduced amounts of gastric acid** in your stomach, as this product may be less effective.

As with other antacid products, Gaviscon Extra Liquid Sachets Peppermint Flavour 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 Liquid Sachets Peppermint Flavour 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 Liquid Sachets Peppermint Flavour

This medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed). 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 LIQUID SACHETS PEPPERMINT FLAVOUR

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.

Adults including older people and children 12 years and over

10-20ml (one to two sachets) 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 Liquid Sachets Peppermint Flavour 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 Liquid Sachets Peppermint Flavour

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 Liquid Sachets Peppermint Flavour can cause side effects, although not everybody gets them. Very rare (less than 1 in 10,000) chance of an allergic reaction from the ingredients. Symptoms may include abdominal pain, diarrhoea, nausea, vomiting, itchy skin, rash, skin rash, itching, dizziness, swelling of the face, lips, tongue, or throat, and difficulty in breathing.

Ingestion of large quantities of calcium carbonate, a component of this product, may cause an increase in blood pH (alkalosis), too much calcium in the blood (hypercalcaemia), increased secretion of stomach acid, and constipation. These usually occur following larger than recommended dosages

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 LIQUID SACHETS PEPPERMINT FLAVOUR

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 carton 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.**

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 Liquid Sachets Peppermint Flavour contain

The active substances in a 10ml dose of oral suspension in sachet are sodium alginate (500mg), sodium bicarbonate (213mg) and calcium carbonate (325mg). The other ingredients are carbomer 974P, methyl parahydroxybenzoate (E218) propyl parahydroxybenzoate (E216), sodium saccharin, peppermint flavour, sodium hydroxide, and purified water.

What Gaviscon Extra Liquid Sachets Peppermint Flavour looks like and contents of the pack

Gaviscon Extra Liquid Sachets Peppermint Flavour contain an off-white to cream suspension with the odour and flavour of peppermint.

Gaviscon Extra Liquid Sachets Peppermint Flavour are available in cartons containing 4, 12 or 24 sachets.

Not all pack sizes may be marketed.

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

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

This medicinal product is authorised in the member states of the EA under the following names:

| | |
|----------------|---|
| Belgium | Gaviscon Antizuur-Antireflux Unidose, suspensie voor oraal gebruik |
| Cyprus | Gaviscon Double Action Πόσιμο Εναιώρημα (Liquid Sachets) |
| Czech Republic | Gaviscon Duo Efekt sáčky |
| Denmark | Galieve Double Action, Oral suspension, Enkeltdosisbeholder |
| Finland | Galieve Duo, Oraalisuspensio, Annospussi |
| Germany | Gaviscon Double Action Sachet 500 mg / 213 mg / 325 mg Suspension zum Einnehmen |
| Greece | Gaviscon Double Action Πόσιμο Εναιώρημα (Liquid Sachets) |
| Hungary | Gaviscon Duo Aktiv borsmenta iz bels leges szuszpenzio tasakban |
| Iceland | Galieve Double Action, Mixtura, dreifa, Skammtapoki |

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|-----------------|---|
| Ireland | Gaviscon Extra Liquid Sachets Peppermint Flavour sodium alginate 500mg/10ml, sodium bicarbonate 213mg/10ml, calcium carbonate 325mg/10ml |
| Italy | Gaviscon Double Action |
| Luxembourg | Gaviscon Antiacide-Antireflux Unidose, suspension buvable |
| Netherlands | Gaviscon Duo Pepermunt suspensie sachets |
| Norway | Galieve Duo, Mikstur, suspensjon, Dosepose |
| Poland | Gaviscon Duo |
| Portugal | Gaviscon Duefet |
| Slovak Republic | Gaviscon Duo Efekt vrecká |
| Sweden | Galieve Duo, Oral suspension, Dospase |
| UK | Gaviscon Double Action Liquid Sachets Peppermint Flavour |

This leaflet was last revised in 03/2016.