

## Package leaflet: Information for the user

Gaviscon Extra Liquid Sachets  
Peppermint Flavour Oral Suspension  
Sodium Alginate 500 mg / 10 ml, Sodium Bicarbonate 213 mg / 10 ml  
Calcium Carbonate 325 mg / 10 ml

### **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 any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### **What is in the 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
3. How to take Gaviscon Extra Liquid Sachets Peppermint Flavour
4. Possible side-effects.
5. How to store Gaviscon Extra Liquid Sachets Peppermint Flavour
6. Contents of the pack and other information.

#### **1. What are Gaviscon Extra Liquid Sachets Peppermint Flavour and what they are used for?**

Gaviscon Extra Liquid Sachets Peppermint Flavour is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate which works 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 Liquid Sachets Peppermint Flavour**

**Do not take Gaviscon Extra Liquid Sachets Peppermint Flavour if you know you are allergic** (hypersensitive) 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 disturbances 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
- 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 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 Liquid Sachets Peppermint Flavour**

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

It also contains 127.88 mg (5.56 mmol) sodium per 10 ml / 1 sachet dose. The maximum recommended daily dose of this medicinal product contains 1023 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 Liquid Sachets Peppermint Flavour on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

It also contains 130mg (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 – 20 ml (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 or 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, 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](http://www.hpra.ie).

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

#### **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 medicine after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. **Do not refrigerate or freeze.**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Gaviscon Extra Liquid Sachets Peppermint Flavour contains**

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

##### **What Gaviscon Extra Liquid Sachets Peppermint Flavour look 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 and Manufacturer**

Reckitt Benckiser Ireland Limited, 7 Riverwalk, Citywest Business Campus, Dublin 24.

##### **Manufacturer:**

RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

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