

# LEAFLET TEXT

## Package leaflet: information for the user

Gaviscon Advance Oral Suspension  
Sodium alginate 500mg, Potassium hydrogen carbonate 100mg.

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

### 1. What Gaviscon Advance is and what it is used for

Gaviscon Advance 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.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### 2. What you need to know before you take Gaviscon Advance

#### Do not take Gaviscon Advance:

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

#### Warnings and Precautions

**This medicine contains 57.85 mg sodium** (main component of cooking/table salt) in each 5 ml dose. This is the equivalent of 2.9% of the recommended maximum daily dietary intake of sodium for an adult.

Gaviscon Advance is indicated for short term treatment only unless advised by your healthcare professional. Talk to your pharmacist or doctor if you need Gaviscon Advance on a daily basis for a prolonged period of time or on a regular basis, especially if you have been advised to have a low salt diet.

**This medicine contains 1.0 mmol (39.06 mg) potassium** per 5 ml dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

**This medicine contains 40 mg calcium** per 5 ml dose.

If you have been advised to follow a diet restricted in any of these please consult your doctor before taking this product.

Also talk to your doctor or pharmacist if you need four or more daily doses for a prolonged period or if you suffer or have suffered from significant kidney or heart diseases, as certain salts could interfere with these diseases.

**This medicine contains 0.525 mg benzyl alcohol** in each 5 ml. Benzyl alcohol may cause allergic reactions.

As your doctor or pharmacist for advice if you are pregnant, 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').

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

#### **Other medicines and Gaviscon Advance:**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Wait at least 2 hours between taking this medicine and other medicines such as tetracyclines, fluoroquinolones (types of antibiotics), iron salts, thyroid hormones, chloroquine (a medicine used to prevent malaria), bisphosphonates (a medication used to treat osteoporosis) and estramustine (a medicine to treat prostate cancer).

#### **Pregnancy and breast-feeding:**

You can take this product if you are pregnant or breast-feeding.

#### **Driving and using machines:**

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

### **3. How to take Gaviscon Advance**

Always take Gaviscon Advance 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.

For oral administration.

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

#### **The recommended dose is:**

Adults, including the elderly and children 12 years and over: 5–10 ml (one to two 5ml spoonfuls) after meals and at bedtime.

#### **Use in children and adolescents:**

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

**If you forget to take Gaviscon Advance:**

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

**If you take more Gaviscon Advance than you should:**

If you take too much of this product you may feel bloated and experience some abdominal discomfort. It is unlikely to cause you any harm, but please consult your doctor or pharmacist if this doesn't go away.

If symptoms persist after 7 days consult your doctor.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. 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. Uncommonly reported side effects are diarrhoea, nausea and vomiting.

**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](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 Advance**

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

Do not use this product after the expiry date (EXP: month/year) shown. The expiry date refers to the last day of that month.

Use within 6 months of opening.

Do not refrigerate.

Do not throw away medicines via wastewater or household waste. Ask your doctor or 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 Advance contains:**

Each 5 ml of oral suspension contains 500 mg sodium alginate and 100 mg potassium hydrogen carbonate as the active ingredients.

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

This product does not contain sugar or gluten.

**What Gaviscon Advance looks like and contents of the pack:**

Gaviscon Advance is available in bottles of 150 ml, 300 ml, 500 ml or 600 ml only from the pharmacy. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer: RB NL Brands BV. Schiphol Blvd 207, 1118 BH Schiphol, NL.

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

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria - Gaviscon Liquid forte Anis 100 mg/ml + 20 mg/ml Suspension zum Einnehmen

Belgium - Gaviscon Advance suspensie voor oraal gebruik/suspension buvable/Suspension zum Einnehmen

Ireland - Gaviscon Advance Oral Suspension

Italy - Gaviscon Advance, sospensione orale

Luxembourg - Gaviscon Advance suspension buvable

Poland - Gaviscon Advance

United Kingdom - Gaviscon Advance Oral Suspension

This leaflet was last revised in upon approval

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