

Package leaflet: Information for the user

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

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

Always take 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 effect
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

This product 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, 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 of 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 disease, as certain salts could interfere with these diseases.

This medicine contains methyl (E218) and propyl (E216) parahydroxybenzoates which 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 medication used to prevent malaria), bisphosphonates (a medication used to treat osteoporosis) and estramustine (a medication 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 this medicine exactly as described in this leaflet or as your pharmacist had told you. Check with your pharmacist if you are not sure.

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. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie

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 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 Advance contains:

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

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

This product does not contain sugar or gluten.

What this product looks like and contents of the pack:

This product 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 B.V. 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:

Germany - Gaviscon Advance Pfefferminz 1000 mg/200 mg Suspension zum Einnehmen

Ireland - Gaviscon Advance Peppermint Oral Suspension

Italy - Gaviscon Advance, Sospensione orale aroma menta

United Kingdom - Gaviscon Advance - Peppermint Flavour

This leaflet was last revised in Upon Approval

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