LEAFLET TEXT

Package leaflet: Information for the use

Gaviscon Advance Chewable Tablets
Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
This medicine is available without prescription. However, you will still need to take this medicine carefully to get the best results from it.
Always us this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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, pharmacist or nurse. 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 Chewable Tablets are and what they are used for
2. What you need to know before taking Gaviscon Advance Chewable Tablets
3. How to take Gaviscon Advance Chewable Tablets
4. Possible side effects
5. How to store Gaviscon Advance Chewable Tablets
6. Contents of the pack and other information

1. What Gaviscon Advance Chewable Tablets are and what they are used for

Gaviscon Advance Chewable Tablets belong 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 Chewable Tablets

Do not take Gaviscon Advance Chewable Tablets if you know you are allergic to any of the ingredients of this medicine (listed in section 6).
If symptoms persist after 7 days consult your doctor.

Warnings and precautions:
This medicine contains 53.22 mg of sodium (main component of cooking/table salt) per tablet. This is equivalent of 2.7% of the recommended maximum daily dietary intake of sodium for an adult.

Gaviscon Advance Chewable Tablets is indicated for short term treatment only unless advised by your healthcare professional. Talk to your pharmacist or doctor if you need Gaviscon Advance Chewable Tablets 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 also contains 1.01 mmol (39.43 mg) potassium per tablet. 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 tablet.

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 if you suffer or have suffered from significant kidney or heart disease, as certain salts could interfere with these diseases.

This product contains 4.5 mg aspartame (E951) per tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Other medicines and Gaviscon Advance Chewable Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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, breast-feeding and fertility
You can take this product if you are pregnant or breast-feeding.

3. How to take Gaviscon Advance Chewable Tablets

Always take Gaviscon Advance Chewable Tablets 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. Chew thoroughly before swallowing.

The recommended dose is:
Adults, including the elderly and children 12 years and over: When symptoms occur take one to two tablets after meals and at bedtime, or as directed.

Use in children and adolescents:
Children under 12 years: should only be taken on medical advice.

If you take more Gaviscon Advance Chewable Tablets than you should you may feel bloated and experience abdominal discomfort. It is unlikely to cause you any harm, but please consult you doctor or pharmacist.

If you forget to take Gaviscon Advance Chewable Tablets it is not necessary to double the dose next time, just carry on taking as before.

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) 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 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

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

5. How to store Gaviscon Advance Chewable Tablets

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

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

Do not store above 30^{o}C

Store in the original package.

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 Chewable Tablets contain

Each chewable tablet contains 500 mg sodium alginate and 100 mg potassium hydrogen carbonate as the active ingredients.

These tablets also contain mannitol (E421), calcium carbonate, polyethylene glycol 20,000, copovidone, magnesium stearate, aspartame (E951), acesulfame potassium and mint flavour.

What Gaviscon Advance Chewable Tablets looks like and contents of the pack

An off-white to cream, circular, flat with bevelled edges tablet with the odour and flavour of peppermint.

Tub containing 20 tablets. One, two, three or four tubes in a carton (pack sizes 20, 40, 60 or 80).

Blister tray containing six individually sealed tablets. Two or four blister trays in a carton (pack sizes 12 or 24).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Manufacturer: RB NL Brands BV. Schiphol Blvd 207, 1118 BH Schiphol, NL.

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

For product queries or comments please call (01) 6305429.

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

Ireland - Gaviscon Advance Chewable Tablets

Italy - Gaviscon Advance compresse masticabili

United Kingdom - Gaviscon Advance Tablets

This leaflet was last revised in: February 2023