

Package leaflet: Information for the user

Gaviscon Peppermint Chewable Tablets

Sodium alginate 250mg, Sodium hydrogen carbonate 133.5mg, Calcium carbonate 80mg

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, 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 the leaflet

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2. What you need to know before you take Gaviscon Peppermint Tablets
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1. What Gaviscon Peppermint Tablets are and what they are used for?

Gaviscon Peppermint Tablets form a protective layer which floats above the contents of the stomach. This layer prevents stomach acid escaping from the stomach into the food pipe, thus relieving the burning feeling of heartburn and the feeling of discomfort in the throat and mouth.

Heartburn may occur following meals (e.g. when eating fatty or spicy food) or during pregnancy, or in patients with symptoms related to an inflammation in the wall of the food pipe (e.g. difficult and/or painful swallowing, mouth sores, vomiting).

Gaviscon Peppermint Tablets are 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, and in patients with symptoms related to eosophagitis.

2. What you need to know before you take Gaviscon Peppermint Tablets

Do not take Gaviscon Peppermint Tablets:

If you know that you are allergic (hypersensitive) to any of the ingredients of Gaviscon Peppermint Tablets as very rarely difficulty in breathing and skin rashes have occurred (see further information for a full list).

Warnings and Precautions

Take special care with Gaviscon Peppermint Tablets:

This medicine contains sodium (5.3 mmol per two tablet dose) and calcium (1.6 mmol per two tablet dose). The maximum recommended daily dose of this medicinal product contains

1012 mg sodium (found in table salt). This is equivalent to 50.6% of the adult recommended maximum daily dietary intake for sodium.

Gaviscon Peppermint Tablets are indicated for short term treatment only unless advised by your healthcare professional. Talk to your pharmacist or doctor if you need Gaviscon Peppermint 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.

Please also talk to your doctor regarding these salt contents if you suffer or have suffered from significant kidney or heart disease, as certain salts could interfere with these diseases.

If symptoms persist after 7 days please consult your doctor.

This medicine contains 3.75 mg aspartame in each table. Aspartame is broken down into phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up in the body because it cannot be removed properly.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Other medicines and Gaviscon Peppermint Tablets

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 including medicines obtained without prescription.

Pregnancy, breast-feeding and fertility:

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

Important information about some of the ingredients of Gaviscon Peppermint Tablets

If you have phenylketonuria, note that the product is sweetened with aspartame, a source of phenylalanine.

3. How to take Gaviscon Peppermint Tablets

For oral administration. Chew thoroughly before swallowing.

Adults, including the elderly and children 12 years and over: When symptoms occur take two to four tablets after meals and at bedtime, up to four times a day.

Children under 12 years old: Should only be given on medical advice.

If you take more Gaviscon Peppermint Tablets than you should: If you take too much of this product you may feel bloated and experience some abdominal discomfort. Consult your doctor or pharmacist if this doesn't go away.

If you forget to take Gaviscon Peppermint Tablets

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 Peppermint Tablets can cause side effects although not everybody gets them.

If you experience these side-effects, stop taking the product and consult your doctor immediately. Very rare (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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

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

5. How to store Gaviscon Peppermint Tablets

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use Gaviscon Peppermint Tablets after the expiry date which is stated on the blister and carton {EXP: month/year}. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 other information

What Gaviscon Peppermint Tablets contains

The active substances in each chewable tablet are 250 mg sodium alginate, 133.5 mg sodium hydrogen carbonate and 80 mg calcium carbonate. The other ingredients are mannitol (E421), macragol 20,000, copovidone, aspartame (E951), peppermint flavouring, magnesium stearate and acesulfame potassium.

What Gaviscon Peppermint Tablets look like and contents of the pack

Gaviscon Peppermint Tablets are circular tablets with an off white to cream, slightly mottled appearance.

8 chewable tablets

16 chewable tablets

20 chewable tablets

24 chewable tablets

32 chewable tablets

48 chewable tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

The marketing authorisation holder is Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24.

This medicine is manufactured by: Reckitt Benckiser Healthcare (UK) Ltd., Hull, HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

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

Belgium – Gaviscon aangepaste formule munt 250 mg kauwtabletten;

France – Gavisconell sans sucre menthe, comprimé à croquer edulcore à l'acesulfame potassique;

Germany – Gaviscon Pfefferminz 250 mg/ 133,5 mg/ 80 mg Kautabletten;

Holland – Gaviscon pepermunt, kauwtabletten

Luxemburg – Gaviscon formule adaptée menthe 250 mg comprimés à croquer;

This leaflet was last revised in upon approval