



GAVISCON PEPPERMINT CHEWABLE TABLETS

Sodium alginate 250mg
Sodium hydrogen carbonate 133.5mg
Calcium carbonate 80mg
Patient Information Leaflet

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

What is in this leaflet:

1. What are Gaviscon Peppermint Tablets and what are they used for?
2. What you need to know before you take Gaviscon Peppermint Tablets.
3. How to take Gaviscon Peppermint Tablets.
4. Possible side effects.
5. How to store Gaviscon Peppermint Tablets.
6. Contents of the pack and other information.

1. WHAT ARE GAVISCON PEPPERMINT TABLETS AND WHAT ARE THEY 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 oesophagitis.

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).

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

Other medicines and Gaviscon Peppermint Tablets:

Do not take this product 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 and breast-feeding:

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: 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. It is unlikely to cause you any harm, but please consult your doctor or pharmacist.

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.

BB85696

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 HPRC/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 on 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 contain

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), macrogol 20,000, copovidone, aspartame (E951), peppermint flavouring, magnesium stearate and acesulfame potassium.

These tablets do not contain sugar or gluten.

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 Manufacturer

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

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

This medicinal product is authorised in the member states of the EEA under the following names: Belgium – Gaviscon aangepaste formule munt 250 mg kauwtabletten; France – Gavisconell sans sucre menthe, comprimé à croquer édulcoré à l'acésulfame potassique; Germany – Gaviscon Pfefferminz 250 mg/ 133,5 mg/ 80 mg Kautabletten; Holland – Gaviscon 250mg 250 peppermint, kauwtabletten; Luxemburg – Gaviscon formule adaptée menthe 250 mg comprimés à croquer; UK – Gaviscon Peppermint Tablets

This leaflet was last approved in May 2017

BB85696

GAVISCON PEPPERMINT CHEWABLE TABLETS

**Sodium alginate 250mg
Sodium hydrogen carbonate 133.5mg
Calcium carbonate 80mg
Patient Information Leaflet**

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

What is in this leaflet:

- 1. What are Gaviscon Peppermint Tablets and what are they used for?**
- 2. What you need to know before you take Gaviscon Peppermint Tablets.**
- 3. How to take Gaviscon Peppermint Tablets.**
- 4. Possible side effects.**
- 5. How to store Gaviscon Peppermint Tablets.**
- 6. Contents of the pack and other information.**

1. WHAT ARE GAVISCON PEPPERMINT TABLETS AND WHAT ARE THEY 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 oesophagitis.

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).

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

Other medicines and Gaviscon Peppermint Tablets:

Do not take this product 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 and breast-feeding:

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: 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. It is unlikely to cause you any harm, but please consult your doctor or pharmacist.

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.

RB857081

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 on 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 contain

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), macrogol 20,000, copovidone, aspartame (E951), peppermint flavouring, magnesium stearate and acesulfame potassium.

These tablets do not contain sugar or gluten.

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 Manufacturer

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

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

This medicinal product is authorised in the member states of the EEA under the following names: Belgium – Gaviscon aangepaste formule munt 250 mg kauwtabletten; France – Gavisconell sans sucre menthe, comprimé à croquer édulcoré à l'acesulfame potassique; Germany – Gaviscon Pfefferminz 250 mg/ 133,5 mg/ 80 mg Kautabletten; Holland – Gaviscon 250mg 250 peppermunt, kauwtabletten; Luxemburg – Gaviscon formule adaptée menthe 250 mg comprimés à croquer; UK – Gaviscon Peppermint Tablets

This leaflet was last approved in May 2017

RB857081