

Package Leaflet: information for the user

GAVISCON SACHETS ORAL POWDER FRESH TROPICAL FLAVOUR

Sodium alginate

Sodium hydrogen carbonate

Calcium carbonate

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

Always use this medicine exactly as described in this leaflet or as your 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. This includes any possible side effect not listed in this leaflet.**

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 Sachets Oral Powder Fresh Tropical Flavour is and what it is used for**
- 2. What you need to know before you take Gaviscon Sachets Oral Powder Fresh Tropical Flavour**
- 3. How to take Gaviscon Sachets Oral Powder Fresh Tropical Flavour**
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1. What Gaviscon Sachets Oral Powder is and what it is used for.

Gaviscon Sachets Oral Powder forms 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 Sachets Oral Powder 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, and in patients with symptoms related to oesophagitis.

2. What you need to know before you take Gaviscon Sachets Oral Powder

Do not take Gaviscon Sachets Oral Powder:

- if you know you are allergic to sodium alginate, calcium carbonate or sodium hydrogen carbonate or any of the other ingredients of this medicine (listed in section 6) as very rarely difficulty in breathing and skin rashes have occurred.**
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Warnings and precautions

Talk to your pharmacist before taking Gaviscon Sachets Oral Powder

This medicine contains sodium (5.3mmol per dose (sachet)) and calcium (1.6mmol per dose (sachet)).

- 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.

You should also consult your doctor if you are over 40 years and have never suffered with heartburn and acid indigestion before.

If symptoms persist after 7 days consult your doctor.

Other medicines and Gaviscon Sachets Oral Powder:

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.

This is especially important if you are taking antibiotics (tetracyclines and quinolones such as norfloxacin), iron preparation, antifungals such as ketoconazole, digoxin and beta-blockers (for heart conditions), neuroleptics (for mental illness), thyroid hormone, chloroquine (for malaria), estramustine (for prostate cancer) and bisphosphonates (for osteoporosis).

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breastfeeding.

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

Gaviscon Sachets Oral Powder contains aspartame.

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

3. How to take Gaviscon Sachets Oral Powder

For oral administration without water.

Pour the contents of the sachet directly onto the tongue.

Always take this medicine 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.

Adults, including the elderly and children 12 years and over: When symptoms occur take one to two single dose containers (sachets) after meals and at bedtime, up to four times a day.

Use in children **under 12 years**: Should only be taken on medical advice.

If you take more Gaviscon Sachets Oral Powder 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.

If you forget to take Gaviscon Sachets Oral Powder

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

If you have any further questions on the use of this product, ask your doctor.

4. Possible Side Effects

Like all medicines, Gaviscon Sachets Oral Powder can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking the product and consult your doctor immediately; Very rarely (less than 1 in 10,000 patients treated) 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.

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 HPRAs 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 Sachets Oral Powder

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

Do not store above 25°C

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 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 to protect the environment.

6. Contents of the pack and other information

What Gaviscon Sachets Oral Powder contain:

The active substances in each sachet are sodium alginate 500mg, sodium hydrogen carbonate 267mg and calcium carbonate 160mg. The other ingredients are mint flavour, passion fruit flavour, macrogol 20,000, macrogol 400, aspartame (E951), citric acid anhydrous, acesulfame potassium (E950), xylitol and silicon dioxide.

What Gaviscon Sachets Oral Powder looks like:

Each sachet contains a cream coloured powder.

Available in packs containing 4, 6, 12, 20, 24, 32 sachets in either a carton or blister pack composed of a cardboard backing card and plastic front.

Not all pack sizes /types may be marketed.

Marketing Authorisation Holder and Manufacturer:

Licence holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. Manufacturer Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull HU8 7DS, United Kingdom.

This medicinal product is authorised in the member state of the EEA under the following names:

United Kingdom	GAVISCON Fizzolve Oral Powder Fruit Flavour
Belgium/Luxemburg	GAVISCON Instants Poeder Voor Oraal gebruik passievrucht
Ireland	GAVISCON Sachets Oral Powder Tropical Flavour
France	GAVISCONELL fruits de la passion, poudre orale en sachet dose
The Netherlands	GAVISCON Instants fresh tropical Poeder Voor Oraal gebruik

This leaflet was last revised in [11/2013]

MULTI-LINGUAL PACK TEXT
Only to be used when there is limited pack space

PROPOSED SACHET LABELLING (SMALL IMMEDIATE PACKAGE UNIT)

1. NAME OF THE MEDICAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Gaviscon Sachets Oral Powder Fresh Tropical Flavour
Sodium alginate, Sodium hydrogen carbonate and Calcium carbonate

2. METHOD OF ADMINISTRATION

Adults and children 12 years and over. One or two single dose sachets after meals and at bedtime. The product is taken orally without water.

3. EXPIRY DATE

EXP MM/YYYY

4. BATCH NUMBER

LOT _____

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1.4g

6. OTHER

Contains aspartame, sodium and calcium. Read the package leaflet before use.

PROPOSED LABEL (CARTON OR CARDBOARD BACKING)

1. NAME OF THE MEDICINAL PRODUCT

Gaviscon Sachets Oral Powder Fresh Tropical Flavour
Sodium alginate, Sodium hydrogen carbonate and Calcium carbonate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each sachet contains 500 mg sodium alginate, 267 mg sodium hydrogen carbonate and 160 mg calcium carbonate.

3. LIST OF EXCIPIENTS

Contains aspartame, sodium and calcium See leaflet for more information.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral powder.
4, 6, 12, 16, 20, 24, 32 sachets.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

If symptoms persist after 7 days consult your doctor.

8. EXPIRY DATE

EXP MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd.
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

PA 979/15/9

13 BATCH NUMBER

LOT _____

14. GENERAL CLASSIFICATION FOR SUPPLY

Pharmacy Only

Or

GSL: Maximum pack size 24 sachets

15. INSTRUCTIONS ON USE

Adults and children 12 years and over: 1 to 2 sachets after meals and at bedtime.

Pour the contents of one sachet directly onto the tongue. To be taken without water.

16. INFORMATION IN BRAILLE

Gaviscon Sachets Oral Powder Fresh Tropical Flavour
