

PROPOSED LEAFLET TEXT (HANDY PACK PRESENTATION)

GAVISCON STRAWBERRY CHEWABLE TABLETS

Sodium alginate 250mg

Sodium hydrogen carbonate 133.5mg

Calcium carbonate 80mg

These tablets bring relief from the pain and discomfort of heartburn and acid indigestion, which for example, can occur after meals or during pregnancy. This product belongs to a group of medicines called “reflux suppressants”, which form a protective layer on top of the stomach contents to prevent stomach acid escaping from the stomach where it works into the food pipe causing pain and discomfort.

BEFORE TAKING THIS PRODUCT: **Do not take** if you know that you are allergic to any of the ingredients (see further information for a full list).

Each four tablet dose contains 10.6 mmol of sodium and 3.2 mmol of calcium. 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 you have phenylketonuria, note that the product is sweetened with aspartame a source of phenylalanine.

Please consult your doctor if you know you have reduced amounts of gastric acid in your stomach, as this product may be less effective.

You can take this product if you are pregnant or breast-feeding. However, the treatment duration should be limited as much as possible.

DOSAGE: 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.

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

If you forget a dose do not double the dose next time, just carry on taking as before. 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.

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.

AFTER TAKING THIS PRODUCT: If symptoms persist after 7 days consult your doctor.

POSSIBLE SIDE EFFECTS: 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. 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 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

FURTHER INFORMATION: These tablets are pale pink, circular, flat with bevelled edges with the odour and flavour of strawberry. The tablets are embossed with a sword and circle on one side, and GS250 on the reverse side. Each chewable tablet contains 250 mg sodium alginate, 133.5 mg sodium hydrogen carbonate and 80 mg calcium carbonate as the active ingredients. The other ingredients are mannitol (E421), macrogol 20 000, aspartame (E951), strawberry flavouring (maltodextrin, modified starch E1450, vegetable oil, propylene glycol E1520), magnesium stearate, red iron oxide, xylitol and carmellose sodium.

These tablets do not contain sugar or gluten.

Do not store above 25°C.

Do not use after the expiry date shown. Use within 6 months of opening

Keep out of the reach and sight of children.

Last revised: month/year.

PROPOSED LEAFLET TEXT (BLISTERS OR HANDY PACKS IN A CARTON)

Package leaflet: Information for the user
GAVISCON STRAWBERRY CHEWABLE TABLETS
Sodium alginate 250mg
Sodium hydrogen Carbonate 133.5mg
Calcium carbonate 80mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for 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 are Gaviscon Strawberry Chewable Tablets and what are they used for
2. What you need to know before you take Gaviscon Strawberry Chewable Tablets
3. How to take this Gaviscon Strawberry Chewable Tablets
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

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

Gaviscon Strawberry Chewable Tablets belong to a group of medicines called “reflux suppressants”, which form a protective layer on top of the stomach contents to prevent stomach acid escaping from the stomach where it works into the food pipe causing pain and discomfort.

Gaviscon Strawberry Chewable Tablets are used for the treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), which may occur, for example, following meals or during pregnancy, and in patients with symptoms related to 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 Strawberry Chewable Tablets

Do not take this product if:

- you know that you are allergic to any of the ingredients as very rarely difficulty in breathing and skin rashes have occurred (see section 6 for a full list).

Warnings and precautions:

This medicine contains sodium (10.6 mmol per four tablet dose) and calcium (3.2 mmol per four 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.

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

Please consult your doctor if you know you have reduced amounts of gastric acid in your stomach, as this product may be less effective.

Taking other medicines:

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.

Pregnancy and breast-feeding:

You can take this product if you are pregnant or breast-feeding. As with all medicines, the treatment duration should be limited as much as possible.

3. How to take Gaviscon Strawberry Chewable 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.

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

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

If you take more than you should you may feel bloated. It is unlikely to cause you any harm, but please consult your doctor or pharmacist.

4. Possible side effects:

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. 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 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

5. How to store this medicine:

Do not use this product after the expiry date (EXP: month/year) shown.

<Handypack only>Use within 6 months of opening.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not store above 25°C.

6. Contents of the pack and other information**What this medicine contains**

Each chewable tablet contains 250 mg sodium alginate, 133.5 mg sodium hydrogen carbonate and 80 mg calcium carbonate as the active ingredients. The other ingredients are mannitol (E421), macrogol 20,000, aspartame (E951), strawberry flavouring (maltodextrin, modified starch E1450, vegetable oil, propylene glycol E1520), red iron oxide, xylitol and carmellose sodium, magnesium stearate. These tablets do not contain sugar or gluten.

What this medicine looks like and contents of the pack

Gaviscon Strawberry Chewable Tablets are pale pink, circular, flat with bevelled edges with the odour and flavour of strawberry. The tablets are embossed with a sword and circle on one side, and GS250 on the reverse side

Gaviscon Strawberry Chewable Tablets are available in pack sizes:

Marketing Authorisation Holder and Manufacturer

Manufacturer UK: Reckitt Benckiser (UK) Ltd., Hull, HU8 7DS.

PA Holder: Reckitt Benckiser Ireland, Ltd., 7 Riverwalk Citywest Business Campus, Dublin 24, Ireland.

For product queries please call: 01-6305429

Gaviscon and (sword symbol) are trademarks.

PA 979/15/5

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

Austria	Gaviscon Erdbeer Kautabletten
Belgium	Gaviscon aardbei 250mg kauwtabletten
Bulgaria	Gaviscon Strawberry Tablets 250 mg/133,5 mg/ 80 mg / Chewable Tablets
Cyprus	Gaviscon Strawberry Tablets
Germany	Gaviscon Erdbeer 250 mg / 133,5 mg / 80 mg Kautabletten
Greece	Gaviscon Strawberry Tablets
France	GAVISCONELL SANS SUCRE FRAISE, comprimé à croquer édulcoré au xylitol, au mannitol et à l'aspartam
Ireland	Gaviscon Strawberry Chewable Tablets Sodium alginate 250mg, Sodium hydrogen carbonate 133.5mg, Calcium Carbonate 80mg
Luxembourg	Gaviscon fraise 250 mg comprimés à croquer
Netherlands	Gaviscon 250 mg aardbei, kauwtabletten
Portugal	Gaviscon Morango, 250 mg + 133.5 mg + 80 mg, Comprimido para mastigar
Romania	Gaviscon cu aromă de căpșuni, comprimate masticabile
United Kingdom	Gaviscon Strawberry Flavour Chewable Tablets

This leaflet was last revised in May 2015