

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Strawberry Flavour Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sodium alginate 250 mg, sodium hydrogen carbonate 133.5 mg, calcium carbonate 80 mg.

Excipient(s) with known effect:

Aspartame (E951)

Sodium

For excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet. (Tablet)

Pale pink, circular, flat with bevelled edges with the odour and flavour of strawberry.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example, following meals or during pregnancy.

4.2 Posology and method of administration

For oral administration, after being thoroughly chewed.

Adults and children 12 years and over: Two to four tablets after meals and at bedtime.

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

Elderly: No dose modifications necessary for this age group.

Hepatic Impairment: No dose modification necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary (see section 4.4).

4.3 Contraindications

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

If symptoms do not improve after 7 days, the clinical situation should be reviewed.

This medicinal product contains 254.84 mg (11.08 mmol) of sodium per four-tablet dose, equivalent to 12.74% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 50.96 % of the WHO adult recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment).

Each four-tablet dose contains 320 mg (3.2 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Due to its aspartame content this product should not be given to patients with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

A time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid

hormones, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, biphosphonates (diphosphonates) and estramustine. See also 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Clinical studies in more than 500 pregnant women as well as a large amount of data from post-marketing experience indicate no malformative nor feto/ neonatal toxicity of the active substances. Gaviscon can be used during pregnancy, if clinically needed.

Breast feeding:

No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. Gaviscon can be used during breast-feeding.

Fertility:

Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction.

Clinical data do not suggest that Gaviscon has an effect on human fertility.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention: very common (1/10), common (1/100 and <1/10), uncommon (1/1000 and <1/100), rare (1/10,000 and <1/1000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Event
Immune System Disorders	Very rare	Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.
Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory effects such as bronchospasm.

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance

of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Symptoms are likely to be minor; some abdominal discomfort may be experienced.

Management

In the event of overdose symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: A02E A01 Anti-regurgitant.

On ingestion Gaviscon Strawberry 250 mg Tablets react rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents, quickly and effectively impeding gastro-oesophageal reflux, for up to 4 hours. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect.

5.2 Pharmacokinetic properties

The mode of action of **Gaviscon Strawberry Flavour Tablets** is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No pre-clinical findings of any relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Macrogol 20,000
Aspartame
Magnesium stearate
Xylitol and Carmellose sodium
Red iron oxide
Strawberry cream flavour (Strawberry cream PHS-048481)
Ingredients of the strawberry cream flavour:
Maltodextrin
Modified starch E1450
Vegetable oil
Propylene glycol E1520

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Unprinted, glass-clear, thermoformable laminate of uPVC/PE/PVdC with aluminium foil lidding blisters packed into cartons.

Pack sizes: 2, 4, 6, 8, 16, 24, 32, 48, 60, 64, 72, 80.

Polypropylene container.

Pack sizes 8, 12, 16, 32.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited,
Dansom Lane,
Hull,
HU8 7DS,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0155.

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

15/10/2024

10 DATE OF REVISION OF THE TEXT

15/10/2024