SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Double Action Mixed Berries Flavour Chewable Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sodium alginate 250 mg, sodium hydrogen carbonate 106.5 mg and calcium carbonate 187.5 mg.

Excipient(s) with known effect:
Aspartame (E951)
Carmoisine Lake (E122)
Sucrose*
Sodium
Mannitol
*present within cranberry and fantasy fruit flavours

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.

A flat, circular, bi-layer tablet with bevelled edges. One layer of the tablet is pink and slightly mottled, and the other white.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of acid related 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, up to four times per day.
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 listed in section 6.1.

4.4 Special warnings and precautions for use

This medicine may cause allergic reactions and may have a mild laxative effect

Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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

Prolonged use should be avoided.

As with other antacid products, taking Gaviscon Double Action Mixed Berries Flavour Chewable Tablets can mask the symptoms of other more serious, underlying medical conditions.

Gaviscon Double Action Mixed Berries Flavour Chewable Tablets should not be used in the following cases:

- Patients with server/impaired renal function/-insufficiency
- Patients with hypophosphatemia

Excipients Warnings:
This medicinal product contains 55.89 mg sodium per dose, equivalent to 2.8 % of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 44.7% of the WHO 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

Each 4 tablet dose contains 300 mg (7.5 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

This medicine contains 5.86 mg aspartame in each Tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the presence of calcium and carbonates which act as an antacid, a time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially H2-antihistaminics, tetracyclines, digoxine, fluoroquinolone, iron salts, thyroid hormones, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, estramustine and diphosphonates. See also section 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy:
A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/neonatal toxicity of the active substances.

Based on this and previous experience the medicinal product may be used during pregnancy and lactation, if clinically needed.

Nevertheless, taking into account the presence of calcium carbonate it is recommended to limit the treatment duration as much as possible.

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

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

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

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events which have been associated with sodium alginate, sodium hydrogen carbonate and calcium carbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: 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); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Very Rare	Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity reactions such as urticaria.
Metabolism and Nutritional Disorders	Not Known	Alkalosis[1], acid rebound[1], Hypercalcaemia[1], Milk-alkali Syndrome[1]
Respiratory, Thoracic and Mediastinal Disorders	Not known	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Very Rare	Abdominal pain, acid rebound, diarrhoea, nausea, vomiting
	Not Known	Constipation[1]
Skin and Subcutaneous Tissue Disorders	Very Rare	Rash Pruritic

Description of Selected Adverse Reactions
1 Usually occurs following larger than recommended dosages.

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

Some abdominal distension may be noticed.

Management

In the event of overdosage symptomatic treatment should be given

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: A02BX, Other drugs for peptic ulcer and gastro-oesophageal reflux disease.

The medicinal product is a combination of two antacids (calcium carbonate and sodium hydrogen carbonate) and an alginate.

On ingestion, the medicinal product reacts rapidly with gastric acid to form a protective barrier (raft) of alginic acid gel having a near neutral pH and which floats on the stomach contents. Effective impediment of gastro-oesophageal reflux may last 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.

Calcium carbonate neutralises gastric acid to provide fast relief from indigestion and heartburn. This effect is increased by the addition of sodium bicarbonate which also has a neutralising action. The total neutralising capacity of the product at the lowest dose of two tablets is approximately 10 mEqH+.

5.2 Pharmacokinetic properties

The mode of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 20,000
Mannitol (E421)
Copovidone
Acesulfame K
Aspartame (E951)
Raspberry flavour
Cranberry flavour (contains sucrose)
Fantasy Fruit flavour (contains sucrose)
Carmoisine Lake (E122)
Magnesium stearate
Xylitol, Carmellose Sodium
Potassium
Sucrose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Blister trays: Do not store above 30°C. Store in the original package to protect from moisture.

6.5 Nature and contents of container

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

Blister tray containing 2, 4, 6 or 8 sealed tablets. Pack sizes: 4, 6, 8, 12, 16, 24, 32, 48, 60, 62, 64 and 80 chewable tablets.

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 00063/0755

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/02/2025

10 DATE OF REVISION OF THE TEXT

18/02/2025