Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Extra Mixed Berries Flavour Chewable Tablets Sodium alginate 250 mg Sodium hydrogen carbonate 106.5 mg Calcium carbonate 187.5 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect:
Aspartame (E951) 5.86 mg per chewable tablet
Carmoisine Lake (E122) 0.375 mg per chewable tablet
Sucrose 1.59 mg per chewable tablet
Sodium 55.936 mg per chewable tablet

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.

A 15 mm flat, circular, bi-layer chewable tablet with bevelled edges. One layer of the chewable tablet is pink and slightly mottled with GDB surface markings, and the other white with sword and circle surface markings.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

The product is indicated in adults and children aged 12 years and over.

4.2 Posology and method of administration

Posology:
Adults and children 12 years and over: Two to four chewable tablets after meals and at bedtime, up to four times per day.

Paediatric:
Children under 12 years: Treatment of children younger than 12 years of age is not recommended.

Elderly:
No dose modifications necessary for this age group.

Hepatic Impairment:
No modifications necessary

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

Method of administration:
For oral administration after being thoroughly chewed.

Duration of treatment:

The recommended maximum duration of use without medical intervention is 7 days. If symptoms do not improve after 7 days, the clinical situation should be reviewed

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

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

Prolonged use should be avoided.

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

Gaviscon Extra Mixed Berries Chewable Tablets should not be used in the following cases:

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

There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

Paediatric population

There is increased risk for hypernatremia in children with gastroenteritis or suspected renal insufficiency.

Treatment of children younger than 12 years of age is not generally recommended.

Excipients

This medicinal product contains 223.7 mg (9.728 mmol) sodium per four chewable tablet dose, equivalent to 11.18% of the WHO recommended maximum daily intake for sodium of 2 g of sodium for an adult.

The maximum daily dose of this product is equivalent to 44.75% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment.

Each four chewable 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 medicinal product contains carmoisine lake (E122) which may cause an allergic reaction.

This medicine contains 5.86 mg aspartame in each chewable tablet. Due to its aspartame (E951) content this product should not be given to patients with phenylketonuria.

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

4.5 Interaction with other medicinal products and other forms of interaction

Due to the presence of calcium and carbonates, which act as antacids, a time-interval of 2 hours should be taken into account between the intake of this medicinal product and the administration of other medicinal products. This applies especially to H_2-antihistaminics, tetracyclines, digoxine, fluoroquinolone, iron salts, thyroid hormones, ketoconazole, neuroleptics, thyroxine, penicillamine, beta-blockers, (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, estramustine and bisphosphonates.
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 if clinically needed.

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], 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 HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

Symptoms
Symptoms are likely to be minor; may experience abdominal discomfort and may notice abdominal distension.

Management
In the event of overdose, symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: A02BX13, Other drugs for peptic ulcer and gastro-oesophageal reflux disease.

The medicinal product is a combination of an alginate and two antacids (calcium carbonate and sodium hydrogen carbonate) which provide protective and neutralising effects.

1. Protective effect
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 ofgastro-oesophageal reflux may last for up to 4 hours. This means that acid regurgitation is mechanically prevented and the oesophagus is thus protected. In severe cases the raft itself instead of the stomach contents may be refluxed into the oesophagus. The raft will then exert a demulcent effect.

2. Neutralising effect
Calcium carbonate and sodium hydrogen carbonate react immediately following ingestion to neutralise gastric acid and provide fast relief from indigestion and heartburn. NAME OF THE MEDICINAL PRODUCT neutralizes the postprandial acid pocket. The total neutralising capacity of the medicinal product at the lowest dose of two chewable tablets is approximately 10 $mEqH^+$. This effect has also been demonstrated in an in vivo study via intragastric pH monitoring using a multi-electrode catheter in fasted healthy participants to remove variability caused by postprandial buffering. The primary study endpoint was the percentage of time with an intragastric pH ≥ 4 during the 30 minutes post-treatment period. This endpoint was achieved 50.8% of the time with sodium alginate -antacid medicinal product versus 3.5% of the time with placebo (p=0.0051).

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 any 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
Mannitol (E421)
Copovidone
Cranberry flavour (Flavouring substance(s), Arabic gum, Potato maltodextrin, Sucrose, Glyceryl triacetate)
Raspberry flavour (Flavouring substance(s), Waxy maize maltodextrin, Propylene glycol (E1520), Modified waxy maize starch)
Fruit flavour (Flavouring substance(s), Arabic gum, Potato maltodextrin, Sucrose, Glyceryl triacetate, Propylene glycol (E1520)
Acesulfame potassium
Aspartame (E951)
Carmoisine Lake (E122)
Magnesium stearate
Xylitol DC (contains carmellose sodium)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 30C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blisters of clear PVC/PE/PVdC laminate with aluminium foil lidding packed into cartons.

Blister tray containing 2, 4, 6 or 8 sealed chewable tablets. Pack sizes: 4, 6, 8, 12, 16, 24, 32, 48, 60, 64, 80 and 112 chewable tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/082/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th October 2023

10 DATE OF REVISION OF THE TEXT