Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Extra Mixed Berries Oral Suspension Sodium alginate 500 mg/ 10 ml sodium hydrogen carbonate 213 mg/ 10 ml Calcium carbonate 325 mg/ 10 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml dose contains 500 mg sodium alginate, 213 mg sodium hydrogen carbonate and 325 mg calcium carbonate.

Excipients with known effect:
Each 10 ml dose contains:
Methyl parahydroxybenzoate (E218) 40 mg
Propyl parahydroxybenzoate (E216) 6 mg
Propylene glycol (E1520) 32 mg
Sodium 128 mg (from excipients, sodium alginate and sodium hydrogen carbonate)

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
An off-white to cream suspension with the odour and flavour of mixed berry.

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: 10-20 ml after meals and at bedtime, up to four times per day.

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. Shake well before use.

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 7 days, the clinical situation should be reviewed.

Prolonged use should be avoided.

As with other antacid products, taking this medicine can mask the symptoms of other more serious, underlying medical conditions.

Gaviscon Extra Mixed Berries Flavour Oral Suspension
500 mg Sodium Alginate 213 mg Sodium Bicarbonate 325 mg Calcium Carbonate should not be used in the following cases:

- Patients with impaired renal function
- 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 recommended.

This medicinal product contains 128 mg (5.56mmol) sodium per 10 ml dose, equivalent to 6% of the WHO recommended maximum daily intake of 2 g of sodium for an adult.

The maximum daily dose of this product is equivalent to 51% 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, e.g. in some cases of congestive cardiac failure and renal impairment.

Each 10 ml contains 130 mg (3.25 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

The medicinal product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

This medicinal product contains 32 mg of propylene glycol in each 10 ml dose.

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 product and the administration of other medicinal products. This applies especially H2-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 nor 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.

Breast-feeding
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 whichhave been associated with sodium alginate, sodium hydrogen carbonate andcalcium carbonate are given below, tabulated by system organ class andfrequency. 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 availabledata). Within each frequency grouping, adverse events are presented in order ofdecreasing 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 via Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms
Some abdominal distension may be noticed.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group, ATC code: 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 of gastro-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, in preference to the stomach contents. 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. The total neutralising capacity of the medicinal product at the lowest dose of 10 ml 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 percentage of time with intragastric pH ≥ 4 during the 30 minutes post-treatment period (primary endpoint) was 50.8% with a sodium alginate-antacid medicinal product versus 3.5% 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

Carbomer
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate, (E216)
Saccharin sodium
Raspberry flavour (Flavouring substance(s), Propylene glycol (E1520))
Cranberry flavour (Flavouring substance(s), Water, Propylene glycol (E1520))
Fruit flavour (Flavouring substance(s), Water, Propylene glycol (E1520))
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Use within 6 months of opening.

6.4 Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and contents of container

Amber glass bottles, or pink coated amber glass bottles, with a polypropylene cap with a polyethylene tamper-evident band lined with expanded polyethylene wad and containing 150, 200, 250, 300, 500 and 600 ml.

May be supplied in cardboard outer carton. May be supplied with a measuring device (natural polypropylene) containing 5 ml, 10 ml, 15 ml, and 20 ml graduations.

Not all pack sizes may be marketed. The carton and measuring device may not be provided in all markets/pack sizes.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited
7 Riverwalk
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA0979/084/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd August 2024

10 DATE OF REVISION OF THE TEXT