Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Extra Chewable TabletsSodium alginate 250mgSodium bicarbonate 106.5mgCalcium carbonate 187.5mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:
Aspartame (E951) 5.863mg per tablet
Carmoisine Lake (E122) 0.375mg per tablet
Sucrose 0.5 mg per tablet

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

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

Posology
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.

Method of administration
For oral administration after being thoroughly chewed

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

Each tablet dose contains 75 mg (1.88 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

This medicinal product contains 55.89 mg sodium per tablet, equivalent to 2.80% of the WHO recommended maximum daily intake for sodium.

The maximum daily dose of this product is equivalent to 44.71% of the WHO recommended maximum daily intake for sodium.

This product is considered high in sodium. This should be taken into account by those on a low salt diet e.g. in some cases of congestive cardiac failure and renal impairment.

This medicinal product contains 5.86 mg aspartame in each tablet. Aspartame is hydrolysed in the gastro-intestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine. Due to its aspartame content this product should not be given to patients with phenylketonuria.

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 Chewable Tablets can mask the symptoms of other more serious, underlying medical conditions.

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

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

There is a possibility of reduced efficacy in patients with very low levels of gastric acid. 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, except on medical advice.

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

4.5 Interaction with other medicinal products and other forms of interactions

Due to the presence of calcium and carbonates which acts 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 bicarbonate 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 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 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 bicarbonate) 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

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 20,000
Mannitol (E421)
Copovidone
Acesulfame K Aspartame (E951)
Mint Flavour Carmoisine Lake
(E122) Magnesium stearate
Xylitol DC (contains carmellose sodium)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Polypropylene container: Use within 3 months of opening.

6.4 Special precautions for storage

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

Flip-top lid containers: Do not store above 25°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 two, four, six or eight sealed tablets. Pack sizes: 4, 6, 8, 16, 24, 32, 48,
60, 62, 64 and 80 chewable tablets.

Coloured, opaque, injection-moulded, polypropylene flip-top lid containers containing 8, 10, 12 or 16 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/015/012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 2010
Date of last renewal: 26th January 2011

10 DATE OF REVISION OF THE TEXT

April 2020