Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Chewable Tablets Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sodium alginate 500 mg and potassium hydrogen carbonate 100 mg.
Excipient with known effect:
Aspartame (E951) (4.5mg per tablet).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.

An off-white to cream, circular, flat with bevelled edges tablet with the odour and flavour of peppermint. Each tablet is imprinted with a Sword and Circle on one side and GA 500 on the reverse

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis.

4.2 Posology and method of administration

Posology

Adults and children 12 years and over: One to two tablets after meals and at bedtime.

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

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

Special Patient Groups:
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.

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.
Each tablet contains 1.0 mmol (40 mg) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
This medicinal product contains 2.3 mmol (53.22 mg) of sodium per tablet, equivalent to 2.7% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 21.28% of the WHO recommended maximum daily intake for sodium. This is based on a two-tablet dose taken four times per day.
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) or when taking drugs which can increase plasma potassium levels.
This medicine contains 1.01 mmol (39.43 mg) potassium per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
This medicine contains 4.5 mg aspartame in each tablet. Aspartame is hydrolysed in the gastrointestinal 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.
May cause central nervous depression in the presence of renal insufficiency and should not be used in patients with renal failure.
For children below 12 years, please see section 4.2.

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 tetracyclines, digoxin, fluoroquinolone, iron salts, thyroid hormones, ketoconazole, neuroleptics, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, estramustine and diphosphonates. See also section 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.

Breastfeeding:
No known effect on breastfed infants. Gaviscon can be used during breastfeeding.

Fertility:
No known effect on human fertility.

4.7 Effects on ability to drive and use machines

Gaviscon has no or negligible influence on the ability to drive or use machines.

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 rarely (1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Event
Gastrointestinal Disorders	Uncommon	Diarrhoea, nausea, vomiting
Immune System Disorders	Very Rare	Anaphlyactic and anaphlyactoid reactions. Hypersensitivity reactions such as urticarial.
Respiratory, Thoracic and Medistinal 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 HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

Symptoms:
Some abdominal discomfort may be experiences. The patient may notice abdominal distension.

Management;
In the event of overdosage symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: A02BX 13. Other drugs for peptic ulcer and gastro oesophageal reflux disease.

On ingestion Gaviscon Advance 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 effectively impeding gastro-oesophageal reflux. 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 Advance 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

Calcium carbonate
Polyethylene glycol 20,000
Mannitol (E421)
Aspartame (E951)
Copovidone
Mint flavour no. 3
Magnesium stearate
Acesulfame potassium

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package.

6.5 Nature and contents of container

White, rigid, injection-moulded, polypropylene cylindrical tube with snap-bead neck finish packed into cartons.

Tube containing 20 tablets. One, two, three or four tubes in a carton.

Container containing 20 or 60 tablets. Pack sizes are comprised of either three 20-tablet containers packed into a carton or one 60-tablet container. For some markets the 60-tablet container will be packed into a carton.

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

12 and 24 blister packs - blister tray containing six individually sealed tablets. Two or four blister trays in a carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/011/008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 2006
Date of last renewal: 5th January 2010

10 DATE OF REVISION OF THE TEXT

February 2023