SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Mint Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sodium alginate 500 mg and potassium bicarbonate 100 mg.

Excipient(s) with known effect:
Sodium 53.22 mg (2.314 mmol)/tablet
Aspartame (E 951) 4.5 mg/tablet
Potassium 39.43 mg/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 "GA500" on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn, indigestion (occurring due to the reflux of stomach contents), for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy, accompanying reflux oesophagitis, including symptoms of laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throats and cough. It can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

4.2 Posology and method of administration

For oral administration, after being thoroughly chewed.

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.

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 Contrindications

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.

This medicinal product contains 53.22 mg 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 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 heart failure and renal impairment).

Potassium: This medicine contains potassium 1.01 mmol (39.43 mg) per tablet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Each two-tablet dose contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

This medicine contains 4.5 mg aspartame (E 951) in each tablet. Aspartame (E 951) 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.

May cause central nervous system depression in the presence of renal insufficiency and should not be used in patients with renal failure.

4.5 Interaction with other medicinal products and other forms of interaction

A time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

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 foeto/neonatal toxicity of the active substances.
Gaviscon can be used during pregnancy, if clinically needed.

Breast feeding:
No known effect on breast fed infants. Gaviscon can be used during breast feeding.

Fertility:
No known effect on human fertility.

4.7 Effects on ability to drive and use machines

None.

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 rare (< 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	Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.
Respiratory, Thoracic and Mediastinal	Very rare	Respiratory effects such as bronchospasm.

Disorders		

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

Symptoms are likely to be minor; some abdominal discomfort may be experienced.

Management

In the event of overdose, 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 the tablet reacts with gastric acid to rapidly form a raft of alginic acid gel having a near-neutral pH which floats on the stomach contents effectively impeding gastro-oesophageal reflux for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases the raft itself may be refluxed into the oesophagus in preference to the stomach contents and exert a demulcent effect. In addition in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within its structure, further protecting the oesophagus from these gastric components.

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

Sodium
Potassium
Mannitol
Calcium carbonate
Macrogol 20,000
Magnesium stearate
Aspartame (E 951)
Mint flavour no. 3
Acesulfame potassium
Copovidone

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 cylinder container with snap-bead neck finish.

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.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0613

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/09/2010 / 29/10/2024

10 DATE OF REVISION OF THE TEXT

29/10/2024