SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Advance Liquid Sachets.

Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml dose contains sodium alginate 500 mg and potassium hydrogen carbonate 100 mg.

Excipients with known effect:
Methyl parahydroxybenzoate (E218) (20 mg / 5ml)
Propyl parahydroxybenzoate (E216) (3 mg / 5ml)
Sodium (57.85 mg / 5ml)

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

Off-white viscous suspension in sachets.

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: 5 – 10 ml after meals and at bedtime.

Children under 12 years: Should only be given 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 use.

Any unused solution should be discarded.

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 including methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) (see section 4.4).

4.4 Special Warnings and Special Precautions for Use

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

Each 5 ml contains 40 mg (1.0 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

This medicinal product contains Methyl hydroxybenzoate and Propyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).

For children below 12 years, please see section 4.2.

This medicinal product contains 57.85 mg (2.5 mmol) sodium, per 5ml dose equivalent to 2.9% of the WHO recommended maximum daily intake of sodium.

The maximum daily dose of this product is equivalent to 23.14% of the WHO recommended maximum daily intake for sodium. This is based on a 10ml 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 heart failure and renal impairment) or when taking drugs which can increase plasma potassium levels.

This medicine contains 1.0 mmol (39.06 mg) per 5 ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

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 timeinterval 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, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), 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 Advance Liquid Sachets 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 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 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 the yellow card scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms
Some abdominal discomfort may be experienced. The patient may notice abdominal distension.

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD).

ATC code: A02BX

On ingestion the suspension reacts 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 mechanism of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3. Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Calcium carbonate
Carbomer 974P
Methyl parahydroxybenzoate E218
Propyl parahydroxybenzoate E216
Saccharin sodium
Peppermint flavour
Sodium hydroxide for pH adjustment

Purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Do not refrigerate.

6.5. Nature and contents of container

A cardboard outer carton containing unit dose stick pack style sachets and a clear injection moulded crystal polystyrene measuring spoon with one bowl containing 2.5ml and 5ml measure. The pack sizes are 2, 4, 10, 12, 20, 24 or 48. Not all pack sizes may be marketed. The spoon may not be made available in all market/pack sizes. The sachets are comprised of polyester, aluminium and polyethylene.
A single sachet, or dual sachets, enclosed in an outer cardboard carton, are also available. Each sachet contains either 5 or 10 ml of medicinal product.

6.6. Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 00063/0112

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/06/2007

10 DATE OF REVISION OF THE TEXT

22/08/2023