

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Gaviscon Advance Tablets

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

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

Excipients with known effect:

Aspartame (E951) (4.5 mg per 1 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

### **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 (53.22mg) 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 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. Due to its aspartame content this product should not be given to patients with phenylketonuria

May cause central nervous system 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 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, 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 fetoneonatal 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 rare (<1/10,000) and not known (cannot be estimated from the available data).

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Event</b>
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](http://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 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**

Mannitol  
Calcium Carbonate  
Polyethylene glycol 20,000  
Magnesium stearate  
Aspartame (E951)  
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 cylindrical tube with snap-bead neck finish packed into cartons.

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

### **7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Healthcare (UK) Limited,

Dansom Lane,

Hull,

HU8 7DS,

United Kingdom.

### **8 MARKETING AUTHORISATION NUMBER(S)**

PL 00063/0144

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

05/01/2010

### **10 DATE OF REVISION OF THE TEXT**

22/08/2023