

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Oral Suspension
500mg/ 10ml Sodium Alginate
267mg/ 10ml Sodium Bicarbonate
160mg/ 10ml Calcium Carbonate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| <u>Active ingredients</u> | <u>mg/10ml</u> |
|---------------------------|----------------|
| Sodium alginate | 500 |
| Sodium bicarbonate | 267 |
| Calcium carbonate | 160 |

Other ingredients include: Methyl parahydroxybenzoate (E218) 40mg/ 10ml and Propyl parahydroxybenzoate (E216) 6mg/ 10ml.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension
An opaque, pink, viscous oral suspension with an odour of fennel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the management of gastric reflux, reflux oesophagitis, hiatus hernia, heartburn (including heartburn of pregnancy) and similar gastric distress.

4.2 Posology and method of administration

Posology

Adults and children over 12 years: 10-20 ml (two to four 5 ml spoonfuls) after meals and before retiring.
Children under 12 years: Should only be given on medical advice.
Children 6-12 years: 5-10 ml (one to two 5 ml spoonfuls) after meals and before retiring.

Special patient groups

Elderly: No dosage modification is required in 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.

Duration of treatment

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

4.3 Contraindications

Hypersensitivity to the active substance or 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 precautions for use

As with all medicines, it is recommended to limit the treatment duration as much as possible. If symptoms do not improve after seven days, the clinical situation should be reviewed.

Each 10 ml dose has a sodium content of 141 mg (6.2 mmol). This should be taken into account when a highly restricted salt diet is recommended.

Calcium: Each dose contains 160 mg of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Due to the presence of calcium and carbonates, 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. See also 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Clinical studies in more than 500 pregnant women as well as a large number 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.

Lactation /breastfeeding:

Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction. No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. Gaviscon can be used during breast-feeding.

Fertility:

Clinical data do not suggest that Gaviscon has an 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 and use machines.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention:

Very rare: < 1/10,000

Not known (cannot be estimated from the available data).

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.

4.9 Overdose

In the event of overdosage symptomatic treatment should be given. The patient may notice abdominal distension.

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 Gaviscon 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 mode of action of Gaviscon Suspension is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No preclinical findings relevant to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Carbomer
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Saccharin sodium
Fennel flavour
Erythrosine soluble
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C. Do not refrigerate.

6.5 Nature and contents of container

Amber glass Type III bottles with a polypropylene cap with a polyethylene tamper-evident band lined with an expanded polyethylene wad containing 200ml or 500ml.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited
7 Riverwalk
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8 MARKETING AUTHORISATION NUMBER

PA 979/15/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First authorisation: 3 May 1978

Date of last renewal: 3 May 2008

10 DATE OF REVISION OF THE TEXT

February 2016