

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Infant, Powder for Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each unit dose sachet of 0.65 g powder contains 225 mg Sodium alginate and 87.5 mg magnesium alginate.
Each doses contains 21 mg sodium.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for Oral Suspension
Sachet containing an off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Gaviscon Infant helps to prevent gastric regurgitation in infants where competence of the cardiac sphincter has not been fully established.

The indications for use are gastric regurgitation, gastro-oesophageal reflux and reflux associated with hiatus hernia in infants and young children.

4.2 Posology and method of administration

If symptoms persist for more than 7 days, or worsen, seek medical advice.

Posology

Infants less than 1 year: Seek medical advice.

Breast fed Infants aged 1 – 2 years:

| Body weight | Dose |
|----------------------------|---|
| Under 4.5kg (10lb) | One sachet - Add 5 mL of cooled, boiled water to the powder in a glass, mix immediately to a smooth paste, add another 10 mL of the water and mix. Give after each feed using a spoon or feeding bottle. |
| Over 4.5 kg (10 lb) | Two sachets – add 5ml of cooled, boiled water to the powder in a glass, mix immediately to a smooth paste, add another 10mL of the water and mix. Give after each feed using a spoon or feeding bottle. |

Bottle fed Infants aged 1 – 2 years:

| Body weight | Dose |
|---------------------------|--|
| Under 4.5kg (10lb) | one sachet to be mixed immediately into not less than 115 mL of each feed in the bottle and shaken well. |

| | |
|---------------------|---|
| Over 4.5 kg (10 lb) | Two sachets to be mixed immediately into not less than 225 mL of each feed in the bottle and shaken well. |
|---------------------|---|

Not appropriate for premature infants, children under 1 year of age except under medical supervision, children over 2 years of age adults or elderly.

Treatment should not be administered more than six times per 24 hours.

Renal Insufficiency: Not to be used when treating infants with known or suspected impairment of renal function (see section 4.3).

Method of Administration:

For oral use after mixing with water or milk feed.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

Contraindicated in cases of intestinal obstruction and in cases of established diarrhoea.

Not to be used except on a doctor or other healthcare professional's recommendation.

Not to be used in situations where excessive water loss is likely, e.g. fever, diarrhoea, vomiting or high room temperature. Not to be used in gastroenteritis where the appropriate treatment is rehydration with fluid replacement.

Not to be used when treating infants with known or suspected impairment of renal function as the sodium content (approximately 21 mg or 0.92 mmol per dose) may add to the risk of hypernatraemia.

4.4 Special warnings and precautions for use

A medical review of the patient’s condition should be undertaken seven days after initiating treatment or before if symptoms worsen.

Follow dosage instructions exactly to avoid an excessive amount of product per feed and the possible risk of hypernatraemia (see section 4.3).

Hypernatraemia should be treated with oral fluids and monitoring of the infant’s electrolytes. Severe cases should be treated by the cautious use of hypo-osmotic solutions.

There have been reports of abnormal stool consistency, e.g. diarrhoea or constipation, with use of this product. Significant or sustained changes in bowel habit should be investigated.

4.5 Interaction with other medicinal products and other forms of interaction

Not to be used with thickening agents or infant milk preparations containing a thickening agent as this could lead to over-thickening of the stomach contents.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Not relevant.

Breastfeeding:
Not relevant.

Fertility:
Not relevant.

4.7 Effects on ability to drive and use machines

Not appropriate.

4.8 Undesirable effects

Gaviscon Infant's mode of action is physical, resulting in a thickening of the gastric contents.

Adverse events which have been associated with sodium alginate and magnesium alginate are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ($\geq 1/10$); Common ($\geq 1/100$ and $< 1/10$); Uncommon ($\geq 1/1000$ and $< 1/100$); Rare ($\geq 1/10,000$ and $< 1/1000$); Very rare ($< 1/10,000$); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

| System Organ Class | Frequency | Adverse Events |
|----------------------------|-----------|---|
| Immune System Disorders | Not known | Hypersensitivity |
| Gastrointestinal Disorders | Very rare | Constipation and diarrhoea |
| | Not known | Intestinal obstruction, flatulence, abdominal distension, and bezoar. |

Description of Selected Adverse Reactions

1. There have been reports of altered stool consistency, including symptoms of constipation and diarrhoea.

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 Pharmacovigilance Section, Health Product Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 676 4971; Fax: +353 1 676 2517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Rare instances have occurred in which an intragastric mass has developed comprising Gaviscon Infant and milk proteins. Overdosage may have contributed to the development of such masses. The majority resolved spontaneously when the child was admitted to hospital, Gaviscon Infant was discontinued and a regime of adequate fluid intake and monitoring of fluid and electrolyte balance was installed. If spontaneous resolution of the mass does not occur, removal by surgical or endoscopic means may be required.

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: A02BX13

The mode of action of Gaviscon Infant is physical. By reacting with acidic gastric contents to form a viscous gel it stabilises stomach activity so reducing the incidence of gastro-oesophageal reflux.

5.2 Pharmacokinetic properties

The mode of action of Gaviscon Infant 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

Mannitol (E421)
Colloidal silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

A cardboard outer carton containing 30 unit dose sachets joined in pairs. The sachets are composed of paper (41 gsm), low density polyethylene (12 gsm), aluminium foil (21.6 gsm), Surlyn (ethylene/methacrylic acid co-polymer neutralized with zinc) 1652 (18 gsm). Two joined sachets enclosed in an outer cardboard wallet are also available.

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

Infant Gaviscon should be mixed with milk or water before taking. As the powder is sterile the sachet should not be opened until immediately before mixing.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0979/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 July 1991

Date of last renewal: 12 July 2006

10 DATE OF REVISION OF THE TEXT

February 2016