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 dose contains 23.9 mg sodium
For a 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 aged 1 to 2 years:
Infants under 4.5kg: use 1 sachet
Infants 4.5kg and over: use 2 sachets

Bottle fed infants:

- Mix each sachet into 115ml of feed in the bottle
- Shake well
- Feed as normal

Breast fed infants and weened infants up to 2 years:

- Mix each sachet with 5ml (1 teaspoon) of cooled boiled water until a smooth paste is formed

- Add another 10ml (2 teaspoons) of cooled boiled water and mix
- For breast fed infants give Gaviscon Infant part way through each feed or meal using a spoon or feeding bottle.
- For all other infants give Gaviscon Infant at the end of each meal using a spoon or feeding bottle.

Treatment should not be administered more than 6 times in any 24 hours.

Not to be used in infants under 1 year of age except under medical supervision

Not suitable for children over 2 years of age, adults or the elderly

Hepatic Impairment: No modification necessary

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

Not to be used in premature infants except under medical supervision

Method of administration

For oral administration

4.3. Contraindications

Hypersensitivity to sodium alginate, magnesium alginate 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 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 23.9 mg or 1.04 mmol per dose) may add to the risk of hypernatraemia.

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

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.

This medicinal product contains 23.9mg sodium per sachet, equivalent to 1% of the WHO recommended maximum daily intake of 2 gm sodium for an adult.
The maximum daily dose of this product is equivalent to 14% of the WHO recommended maximum daily intake for sodium.
This product is considered high in sodium. This should be taken into account for those on a low salt diet.

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. Effect on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

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 (≥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); 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[1]
Gastrointestinal Disorders	Very rare	Constipation and diarrhoea[1]
	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. Hypersensitivity reactions include anaphylactic and anaphylactoid reactions, pruritus, rash and urticaria.

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

On ingestion, the product reacts rapidly with gastric acid to form a low-density but viscous gel. The gel thickens the stomach contents and quickly and effectively impedes gastro-oesophageal reflux.

5.2. Pharmacokinetic properties

The mechanism 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 silicon dioxide

6.2. Incompatibilities

Not applicable**.**

6.3. Shelf-life

Three years.

6.4. Special precautions for storage

Do not store above 30^{o}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) with Surlyn (ethylene/methacrylic acid co-polymer neutralised with zinc) 1652 laminate (18 gsm). Two joined sachets enclosed in an outer cardboard wallet are also available.

6.6. Special precautions for disposal and other handling

Gaviscon Infant should be mixed with milk or water to an off-white colour 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

PA 979/12/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 12th July 1991.
Date of last renewal: 12th July 2006.

10. DATE OF REVISION OF THE TEXT

February 2020