Gaviscon Infant - SmPC

1. Name of the medicinal product

Gaviscon Infant

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.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Sachet of 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

For infants aged 1 to 2 years. Not to be used in premature infants or infants under one year except under medical supervision.

Mix immediately before use as directed below:

Infants under 4.5 kg (10lb) – one sachet should be used

Infants over 4.5kg (10lb) – two sachets should be used

Bottle fed infants:

• Mix each sachet into 115 ml (4 fl oz) of feed in the bottle.

• Shake well

• Feed as normal

Breast fed infants and other infants up to 2 years:

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

• Add another 10 ml (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 six times in any 24 hour period.

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

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 used after mixing with water or milk feed

4.3 Contraindications
Hypersensitivity to sodium alginate and magnesium alginate or 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 health 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.

Significant or sustained changes in bowel habit or stool consistency e.g. diarrhoea or constipation, should be investigated.

Follow dosage instructions exactly to avoid an excessive amount of product per feed and the possible risk of hypernatraemia.

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.

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.

This medicinal product contains 23.9 mg sodium per sachet, equivalent to 1% of the WHO recommended maximum daily intake of 2 g sodium for an adult. The maximum daily dose of this product is equivalent to 14 % of the WHO recommended maximum daily intake for sodium for an adult. This product is considered high in sodium. This should be particularly 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 Effects on ability to drive and use machines
Not applicable.

4.8 Undesirable effects
Gaviscon Infant's mode of action is physical, resulting in a thickening of the gastric contents. An excessive concentration of Gaviscon Infant may lead to gastric distension.

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
Gastrointestinal Disorders	Very rare	Constipation and diarrhoea.
	Not known	Intestinal obstruction, flatulence, abdominal distension and bezoar.

4.9 Overdose
Symptoms

Overdosage with Gaviscon Infant may lead to the formation of an intragastric mass.

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 and colloidal silica.

6.2 Incompatibilities
None known.

6.3 Shelf life
Two 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.

6.6 Special precautions for disposal and other handling
Gaviscon Infant 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

Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd., Hull, UK

Importer: Reckitt Benckiser (Thailand) Ltd., Bangkok, Thailand

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text

12/03/2021