Prescribing information

Prescribing information for Gaviscon Double Action Mint PL 00063/0552
ACTIVE INGREDIENTS: 10ml dose: sodium alginate 500mg, sodium bicarbonate 213mg, calcium carbonate 325mg.
INDICATIONS: Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn and indigestion, e.g. following meals or during pregnancy, and for symptoms of hyperacidity. Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy. DOSEAGE INSTRUCTIONS: For oral use. Adults and children 12yrs and over: 10-20ml after meals and at bedtime, up to 4 times/day. Children under 12yrs.: Only on medical advice. Elderly: No dose modifications necessary. CONTRAINDICATIONS: Hypersensitivity to the active substances or to any of the excipients, including methyl parahydroxybenzoate (parabens). PRECAUTIONS AND WARNINGS: Each 20 ml dose has a sodium content of 254.5 mg (11.06 mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment. Each 20 ml contains 260 mg (6.5 mmol) of calcium. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi. If symptoms do not improve after 7 days, the clinical situation should be reviewed. Due to the presence of calcium carbonate (antacid) an interval of 2 hrs should be considered between Gaviscon intake and the administration of other medicinal products, especially H2-antihistamines tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, and diphosphonates. PREGNANCY AND LACTATION: Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of Gaviscon on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience the medicinal product may be used during pregnancy and lactation. SIDE-EFFECTS: Very rarely (<1/10,000) patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. Ingestion of large quantities of calcium carbonate may cause alkalosis, hypercalcaemia, acid rebound, milk alkali syndrome or constipation. These usually occur following larger than recommended dosages
NHS PRICE: £XXX

Prescribing information for Gaviscon Advance Aniseed Suspension PL 00063/0108
NAME AND ACTIVE: Gaviscon Advance Aniseed Suspension. Each 10ml dose contains sodium alginate 1000.0mg and potassium bicarbonate 200.0mg. INDICATIONS: Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn, indigestion (occurring due to the reflux of stomach contents), for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy, accompanying reflux oesophagitis,

Prescribing information for Gaviscon Advance Peppermint Flavour Suspension PL 00063/0103
NAME AND ACTIVE: Gaviscon Advance – Peppermint Flavour Suspension. Each 10ml dose contains sodium alginate 1000.0mg and potassium bicarbonate 200.0mg. INDICATIONS: Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn, indigestion occurring due to the reflux of stomach contents, for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy or accompanying reflux oesophagitis. DOSAGE AND ADMINISTRATION: Adults and children 12 years and over: 5-10 ml 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. Elderly: No dose modification is required for this age group. Hepatic Impairment: No modifications necessary. CONTRAINDICATIONS: Hypersensitivity to the active substances or to any of the excipients, including methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). PRECAUTIONS AND WARNINGS: If symptoms do not improve after seven days, the clinical situation should be reviewed. Each 10 ml dose has a sodium content of 106 mg (4.6 mmol) and a potassium content of 260 mg (6.5 mmol) of calcium. 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): May cause allergic reactions (possibly delayed). 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 feto/neonatal 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. SIDE EFFECTS: Very rarely (<1/10,000) patients develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. Legal Classification: P Licence Holder: Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom Licence Number: PL 00063/0103 MRRP: £XXX Last Revised: April 2016

Prescribing Information Gaviscon Advance Aniseed Suspension PL 00063/0108
NAME AND ACTIVE: Gaviscon Advance Aniseed Suspension. Each 10ml dose contains sodium alginate 1000.0mg and potassium bicarbonate 200.0mg. INDICATIONS: Treatment of symptoms resulting from the reflux of acid, bile and pepsin into the oesophagus such as acid regurgitation, heartburn, indigestion (occurring due to the reflux of stomach contents), for instance, after gastric surgery, as a result of hiatus hernia, during pregnancy, accompanying reflux oesophagitis,
including symptoms of laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throats and cough. Can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy. **DOSEAGE AND ADMINISTRATION:** Adults and children 12 years and over: 5-10ml after meals and at bedtime. Children under 12 years: Should be given only on medical advice. Elderly: No dose modification is required for this age group. **CONTRAINDICATIONS:** This medicinal product is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients, or any of the excipients, including methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). **PRECAUTIONS AND WARNINGS:** If symptoms do not improve after seven days, the clinical situation should be reviewed. Each 10 ml dose has a sodium content of 106 mg (4.6 mmol) and a potassium content of 78 mg (2.0 mmol). This should be taken into account when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment or when taking drugs which can increase plasma potassium levels. Each 10 ml contains 200 mg (2.0 mmol) 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): May cause allergic reactions (possibly delayed). **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 foeto/neonatal toxicity of the active substance. Gaviscon can be used during pregnancy, if clinically needed. Breast feeding: No known effect on breast fed infants. Gaviscon can be used during breast feeding. **SIDE EFFECTS:** Very rarely (<1/10,000) patients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions. 

**Legal Classification:** P 

**Licence Holder:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom 

**License Number:** PL 00063/0108 

**MRRP:** EXXX 

**Last Revised:** April 2016 

---

**Prescribing Information Gaviscon Infant (sodium alginate and magnesium alginate)**

**NAME AND ACTIVE:** Gaviscon Infant. Each unit dose sachet of 0.65 g powder contains 225 mg sodium alginate and 87.5 mg magnesium alginate. **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. **DOSEAGE AND ADMINISTRATION:** For infants aged 1 to 2 years. Not to be used in premature infants or infants under one year except under medical supervision. For oral use after mixing with water or milk feed, mix immediately before use as directed: For infants under 4.5 kg (10lb) – one sachet should be used. For infants over 4.5kg (10lb) – two sachets should be used. For bottle fed infants, mix each sachet into 115ml (4 fl oz) of feed in the bottle. Shake well and feed as normal. For breast fed infants and other infants up to 2 years, mix each sachet with 5ml (1 teaspoon) of cooled boiled water until a smooth paste is formed. Then 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 six times in 24 hours. Not suitable for children over 2 years, adults or the elderly. Renal Insufficiency: Not to be used when treating infants with known or suspected impairment of renal function. If symptoms persist for more than 7 days, or worsen, seek medical advice. **CONTRAINDICATIONS:** Cases of intestinal obstruction and in cases of established diarrhoea. Hypersensitivity to sodium alginate and magnesium alginate or any of the excipients. 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. Not to be used except on a doctor or other health professional’s recommendation. **PRECAUTIONS:** Follow dosage instructions exactly to avoid an excessive amount of product per feed and the possible 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. Significant or sustained changes in bowel habit or stool consistency e.g. diarrhoea or constipation, should be investigated. A medical review of the patient’s condition should be undertaken seven days after initiating treatment or before if symptoms worsen. 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. **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. Hypersensitivity, intestinal obstruction, flatulence, abdominal distension and bezoar. Frequency unknown. Constipation and diarrhoea very rare frequency (<1/10,000). **Legal Category:** P. **Licence Holder:** Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, United Kingdom. 

**License Number:** PL 00063/0099 

**Presentation and Basic NHS price:** £8.99. 30 unit doses 

**Last revised:** October 2017

---

**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) Ltd on: 0333 200 5345**

---

UK/G-NHS/0818/0015a  
Date of preparation: September 2018