Gaviscon Advance - Peppermint Flavour

Name and Strength of Active Substance(s) Sodium Alginate 1000mg/10ml, Potassium Bicarbonate 200mg/10ml.

Product Description

Off white viscous oral suspension with peppermint odour.

Pharmacodynamics

On ingestion the suspension reacts with gastric acid to rapidly form a raft of alginic acid gel having a near-neutral pH which floats on the stomach contents quickly and effectively impeding gastro-oesophageal reflux for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases the raft itself may be refluxed into the oesophagus in preference to the stomach contents and exert a demulcent effect. In addition, in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within its structure, further protecting the oesophagus from these gastric components.

Pharmacokinetics

The mode of action of the product is physical and does not depend on absorption into the systemic circulation. After emptying from the stomach, the raft disintegrates as it passes through the remainder of the gastrointestinal tract and the components are excreted in the faeces. Some absorption of components may occur, but no safety issues would be expected as all of the components are well known pharmaceutical or food ingredients.

Indication

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. It can also be used to treat the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

Recommended Dose

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.

Route of Administration

Oral

Contraindications

The medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipient.

Warnings and Precautions

This medicinal product contains 115.7 mg (5.0 mmol) sodium per 10 ml dose, equivalent to 5.8% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 23.14% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in some cases of congestive heart failure and renal impairment).

Potassium: This medicine contains 78 mg (2.0 mmol) potassium per 10 ml dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

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.

This medicinal product contains Methyl hydroxybenzoate and Propyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).

If symptoms do not improve after 7 days, the clinical situation should be reviewed.

Interactions with Other Medicaments

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.

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 substances. 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.

Fertility:

No known effect on human fertility.

Side Effects

Adverse reactions have been ranked under headings of frequency using the following convention: 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) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Event
Gastrointestinal Disorders	Uncommon	Diarrhoea, nausea, vomiting.
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.

Symptoms and Treatment of Overdose

Symptoms:

Symptoms are likely to be minor; some abdominal discomfort may be experienced.

Management:

In the event of overdose, symptomatic treatment should be given.

Storage Conditions

Store dry below 30℃. Do not refrigerate.

Shelf Life

2 years

Packaging available:

Bottle: 150 ml, 300ml, 500ml

Sachet: 4's x 10 ml, 5's x 10 ml, 8's x 10 ml, 10's x 10ml, 12's x 10 ml, 24's x 10 ml.

Not all pack sizes may be marketed.

Manufacturer:

Reckitt Benckiser Healthcare (UK) Ltd., Dansom Lane, Hull, East Yorkshire, HU87DS, United Kingdom.

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Product Registration Holder:

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