Gaviscon Double Action Liquid (Mixed Berries Flavour)

Name and Strength of Active Substance(s)
Sodium Alginate 500mg/10ml, Sodium Hydrogen Carbonate 213mg/10ml and Calcium Carbonate 325mg/10ml.

Product Description
Opaque off white viscous oral suspension with odour and flavour of berry.

Pharmacodynamics
On ingestion, Gaviscon reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents effectively (up to 4 hours) impeding gastro-oesophageal reflux. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect. Evidence shows the rapid onset of Gaviscon in soothing relief within 4 minutes.

Pharmacokinetics
The mode of action of this medicinal product is physical and does not depend on absorption into the systemic circulation. Alginate is an indigestible polysaccharide which acts as a source of dietary fiber, eventually breaking down and passing naturally through the digestive system. Bicarbonate/hydrogen carbonate salts such as sodium bicarbonate are absorbed, and in the absence of a deficit of hydrogen carbonate in the plasma, hydrogen carbonate ions are readily excreted in the urine.
Calcium carbonate provides a source of calcium ions which cross-link the alginate molecules and increase the raft strength. Some calcium is absorbed and the rest is excreted through the digestive system.

Indication
Treatment of acid related symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion, for example following meals or during pregnancy.

Recommended Dosage
Adults and children 12 years and over: Take 10-20 ml after meals and before bedtime, up to four times a day.
Children under 12 years old: Should only be taken on medical advice.
Shake well before use.

Route of Administration
Oral

Contraindications
This medication product is contraindicated in patients with known or suspected hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions

Each 10ml dose has a sodium content 127.25mg (5.53mmol). This should be considered when a highly restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment. Each 10 ml contains 130 mg (3.25 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 seven days, the clinical situation should be reviewed. Contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed). Prolonged use should be avoided. As with other antacid products, taking Gaviscon Double Action Mixed Berries Flavour Oral Suspension can mask the symptoms of other more serious, underlying medical conditions. Gaviscon Double Action Mixed Berries Flavour Oral Suspension should not be used in the following cases: Patients with severe/impaired renal function/-insufficiency and/or Patients with hypophosphatemia. There is a possibility of reduced efficacy in patients with very low levels of gastric acid. There is increased risk for hypernatremia in children with gastroenteritis or suspected renal insufficiency. Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Interactions with Other Medicaments

Due to the presence of calcium and carbonates which acts as an antacid, a time-interval of 2 hours should be considered between Gaviscon intake and the administration of other medicinal products, especially H2-antihistaminics, tetracyclines, digoxine, fluoroquinolone, iron salts, thyroid hormones, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, estramustine and diphosphonates.

Pregnancy and Lactation

Pregnancy: A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicates normal formative or feto/neonatal toxicity of the active substances.

Based on this and previous experience, the medicinal product may be used during pregnancy and lactation, if clinically needed.

Nevertheless, taking into account the presence of calcium carbonate it is recommended to limit the treatment duration as much as possible.

Breastfeeding: No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. This product can be use during breast-feeding.

Fertility: Pre-clinical animal investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction. Clinical data do not suggest that this product has an effect on human fertility.

Side Effects

Adverse events which have been associated with sodium alginate, sodium hydrogen carbonate and calcium carbonate 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 (≥1/10,000and <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	System Organ	System Organ
Immune SystemDisorders	Very Rare	Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity reactions such as urticaria.
Metabolism and Nutritional Disorders	Not Known	Alkalosis[1], Hypercalcaemia[1], Milk-alkali
Respiratory, Thoracic and Mediastinal Disorders	Not known	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Very Rare	Abdominal pain, acid rebound, diarrhoea, nausea, vomiting
	Not Known	Constipation[1]
Skin and Subcutaneous Tissue Disorders	Very Rare	Rash Pruritic

Description of Selected Adverse Reactions:
1 Usually occurs following larger than recommended dosages.

Reporting of Suspected Adverse Reactions:
Reporting suspected adverse reactions after authorization 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 to respective authorities.

Symptoms and Treatment of Overdose
Symptoms: - Some abdominal distension may be noticed.
Management: - In the event of overdosage symptomatic treatment should be given.

Storage Conditions
Keep out of the sight and reach of children.
Do not store above 30℃. Do not refrigerate or freeze. Use within 6 months of opening.

Dosage forms and packaging available
Oral Suspension. Available in bottles of 150ml and 300ml. Sachets: 1 unit x 10ml, 4 unit x 10ml, 12unit x 10ml and 24 unit x 10ml.

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