# GAVISCON DOUBLE ACTION LIQUID

Each 10 ml of Gaviscon Double Action Liquid contains sodium alginate 500 mg, sodium bicarbonate 213 mg, calcium carbonate 325 mg.



**PROPRIETARY NAME (AND DOSAGE FORM):**

Gaviscon Double Action Liquid (Suspension)

**SCHEDULING STATUS:**

S0

**PROPRIETARY NAME (AND DOSAGE FORM):**

Gaviscon Double Action Liquid (Suspension)

**COMPOSITION:**

Each 10 ml of Gaviscon Double Action Liquid contains sodium alginate 500 mg, sodium bicarbonate 213 mg, calcium carbonate 325 mg.

Other ingredients include: carbomer 974 P, sodium hydroxide, sodium saccharin, peppermint flavour, methylhydroxybenzoate, propylhydroxybenzoate

**PHARMACOLOGICAL CLASSIFICATION:**

A 11.10 Medicines acting on gastro-intestinal tract. Special combinations.

**PHARMACOLOGICAL ACTION:**

Pharmacodynamic properties:

Sodium alginate reacts with saliva and gastric acid to produce a viscous gel, which floats on the stomach contents suppressing gastric reflux.

Calcium carbonate and sodium carbonate have gastric acid neutralising effect.

Pharmacokinetic properties:

In cases of severe reflux, the gel itself may be refluxed into the oesophagus where it helps protect the mucosa. The mode of action of Gaviscon Double Action Liquid is physical and does not depend on absorption into the systemic circulation.

**INDICATIONS:**

GAVISCON DOUBLE ACTION LIQUID is indicated for the following conditions:

Gastric reflux, reflux oesophagitis and heartburn.

**CONTRA-INDICATIONS**

Hypersensitivity to any of the ingredients.

**WARNINGS AND SPECIAL PRECAUTIONS**

Each 10 ml dose of GAVISCON DOUBLE ACTION LIQUID contains 127.25 mg (5.53 mmol) of sodium. Sodium bicarbonate should be administered with caution in patients with congestive heart failure, renal impairment, cirrhosis of the liver, hypertension, patients receiving corticosteroids, patients with metabolic or respiratory alkalosis, hypocalcaemia, hypochlorhydia or patients on a salt restricted diet.

Each 10 ml dose of GAVISCON DOUBLE ACTION LIQUID 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.

High doses or prolonged use of calcium carbonate may lead to gastric hypersecretion and acid rebound. Hypercalcaemia/alkalosis can occur, especially in patients with renal function impairment or after high doses of calcium carbonate. There have been rare reports of the milk-alkali syndrome associated with calcium carbonate.

Contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Prolonged use of Gaviscon Double Action Liquid should be avoided.

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

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

GAVISCON DOUBLE ACTION LIQUID has no or negligible influence on the ability to drive and use machines.

**INTERACTIONS**

Large doses of GAVISCON DOUBLE ACTION LIQUID may affect the rate and/or the extent of absorption of other oral medicines. A time interval of 2 hours should be considered between GAVISCON DOUBLE ACTION LIQUID intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

Thiazide diuretics and vitamin D – Hypercalcaemia has occurred when calcium salts are given with thiazide diuretics or vitamin D.

**PREGNANCY AND LACTATION**

Pregnancy:

Cljnical studies as well as post-marketing data indicated no malformative nor feto/neonatal toxicity of Gaviscon Double Action Liquid.

Lactation:

No effects of Gaviscon Double Action Liquid have been shown in breastfed newborns/ infants of treated mothers. Gaviscon Double Action Liquid can be used during breastfeeding.

Fertility:

Clinical Data do not suggest that Gaviscon Double Action Liquid has an effect on human fertility.

**DOSAGE AND DIRECTIONS FOR USE:**

For oral administration.

SHAKE WELL BEFORE USE.

| | |
|---|---|
| Adults and children over 12 years: | 10 - 20 ml after meals and at bedtime, up to four times per day.. |
| Children under 12 years: | Should be given only on medical advice. |
| Elderly: | No dosage modifications necessary in this group. |

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**SIDE-EFFECTS:**

Adverse reactions have been ranked under headings of frequency using the following convention: Very common: ≥ 1/10; common: ≥ 1/100 to < 1/10; uncommon: ≥ 1/1,000 to < 1/100; rare: ≥ 1/10,000 to < 1/1,000; very rare: < 1/10,000; Not known: cannot be estimated from the available data.

- **Gastrointestinal disorders:** Uncommon: Stomach cramps, flatulence, constipation. Very rare (<1/10 000): Nausea, vomiting and diarrhoea
- **Immune System Disorders:** Not known: Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity such as Urticaria
- **Respiratory, Thoracic and Mediastinal Disorders**: Not known: Respiratory effects such as Bronchospasm
- **Musculo-skeletal disorders:** Very rare (<1/10 000): Abdominal distension and abdominal cramps

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Very large doses may produce a feeling of abdominal distension. Treatment of overdosage is symptomatic and supportive.

**IDENTIFICATION:**

Gaviscon Double Action Liquid  A viscous, opaque, off-white to cream suspension with a flavour of peppermint.

**PRESENTATION:***

**Bottles**

Amber glass bottles containing 100 ml, 150 ml, 200 ml, 250 ml, 300 ml, 500 ml or 600 ml with a white injection moulded polypropylene (28 mm or 36 mm) caps with red polyethylene tamperproof bands lined with an expanded polyethylene wad

**Sachets**

10 ml Laminate sachets composed of 12µm polyester aluminium foil, 18µm gsm polyethylene, 12µ polyester film, 50 gsm polyethylene.  The aluminium foil sachets are packed in multiples of 2, 10 or 12 sachets per carton. Each sachet is embossed with a product barcode next to the product name.

**STORAGE INSTRUCTIONS:**

Store below 25 °C. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

A40/11.10/0480

**NAME AND BUSINESS ADDRESS OF APPLICANT:**

©Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road,

Elandsfontein

1601

**DATES OF PUBLICATION OF THIS PACKAGE INSERT:**

9 October 2009

*On the printed version, pack sizes may be limited to those actually marketed

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