Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product: Gaviscon Double Action Liquid
Dosage: Suspension
Strength: Each 10 ml contains Sodium alginate 500 mg, sodium bicarbonate 213 mg and calcium carbonate 325 mg.
PI Update: 30 April 2015
PI Safety Update and New Indication: 15 February 2024

1.5.5.1 ANNOTATED PROPOSED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Gaviscon Double Action Liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Preservatives:

Methylhydroxybenzoate 0,4% m/v

Propylhydroxybenzoate 0,06% m/v

Sugar free

Contains sweetener: Sodium saccharin 0,1% m/v

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gaviscon Double Action Liquid is indicated for the following conditions: Gastric reflux, reflux oesophagitis, heartburn and indigestion.

4.2 Posology and method of administration

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Posology

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.

Hepatic Impairment: No dose modification necessary.

Renal Insufficiency: Caution if highly restricted salt diet is necessary (see section 4.4).

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

Method of administration

For oral administration.

SHAKE WELL BEFORE USE.

4.3 Contraindications

Hypersensitivity to sodium alginate, sodium bicarbonate, calcium carbonate, the esters of hydroxybenzoates (parabens) or to any of the excipients listed in section 6.1.

GAVISCON DOUBLE ACTION LIQUID should not be used in patients with moderate or severe renal insufficiency

4.4 Special warnings and precautions for use

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 para-hydroxybenzoate and propyl para-hydroxybenzoate 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.

4.5 Interaction with other medicines and other forms of interaction

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

H2-antihistaminics, tetracyclines, digoxin, fluoroquinolones, iron

salts, thyroid hormones, ketoconazole, neuroleptics, thyroxine, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine, bisphosphonates, and estramustine.

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

4.6 Fertility, pregnancy and lactation

Pregnancy:

Clinical 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.

4.7 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.

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4.8 Undesirable 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.

System Organ Class	**Frequency**	**Adverse Events**
Immune System Disorders	Frequency unknown	Anaphylactic reaction, Anaphylactoid reaction. Hypersensitivity reactions such as urticaria.
Metabolism and Nutritional Disorders	Frequency unknown	Alkalosis[1] Acid rebound[1] Hypercalcaemia[1] Milk-alkali Syndrome[1]
Respiratory, Thoracic and Mediastinal Disorders	Frequency unknown	Respiratory effects such as bronchospasm.
Gastrointestinal Disorders	Less frequent	Stomach cramps Flatulence, Constipation[1] Nausea Vomiting Diarrhoea
Musculo-skeletal Disorders	**Less frequent**	Abdominal distension Abdominal cramps

Description of Selected Adverse Reactions

[1]Usually occurs following larger than recommended dosages.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Contact details for the reporting of side effects: 0861 11 1100

4.9 Overdose

Symptoms

Very large doses may produce a feeling of abdominal distension. Milk-alkali syndrome has occurred in individuals taking large doses of calcium carbonate per day for prolonged periods.

Management

Treatment of overdosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

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

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease: ATC Code: A02BX

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.

5.2 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.

5.3 Preclinical safety data

No pre-clinical findings of any relevance to the prescriber have been reported.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 974 P

Sodium hydroxide (pH adjuster)

Sodium saccharin (sweetener)

Peppermint flavour

Methyl p-hydroxybenzoate (preservative)

Propyl p-hydroxybenzoate (preservative)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Do not refrigerate.

6.5 Nature and contents of container*

Bottles

Amber glass bottles containing 150 ml, 300 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 12 µm polyester aluminium foil, 18 µm gsm polyethylene, 12 µ polyester film, 50 gsm

polyethylene. The aluminium foil sachets are packed in multiples of 12 or 24 sachets per carton. Each sachet is embossed with a product barcode next to the product name.

6.6 Special precautions for disposal and other handling

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

©Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road,

Elandsfontein

1601

8. REGISTRATION NUMBER:

A40/11.10/0480

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9 October 2009

10. DATE OF REVISION OF THE TEXT

16 August 2024

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

REFERENCES

REFERENCE NO.	TITLE
1	Gaviscon Double Action Aniseed Oral Suspension-UK-SmPC-19.12.22
2	2.5 clinical-overview ZA -Apr21