**SCHEDULING STATUS:**

S0

**PROPRIETARY NAME AND DOSAGE FORM:**

**Gaviscon Peppermint Tablets**

**COMPOSITION:**

Each tablet contains 250 mg of sodium alginate, 133,5 mg of sodium bicarbonate and 80 mg of calcium carbonate.

Other ingredients: mannitol; macrogol 20,000; magnesium stearate and peppermint flavour.

Contains sweetener (Acesulfame K 3,75 mg, Aspartame 3,75 mg per tablet).

**PHARMACOLOGICAL CLASSIFICATION:**

A 11.10 Medicines acting on gastro-intestinal tract, special combinations.

**PHARMACOLOGICAL ACTION:**

**Pharmacodynamic properties**

Sodium bicarbonate and calcium carbonate have acid neutralising properties.

**Pharmacokinetic Properties**

The mode of action of the tablets is physical and does not depend on absorption into the systemic circulation.

Alginate reacts with gastric acid to form a viscous gel.

**INDICATIONS:**

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

**CONTRA INDICATIONS:**

Known hypersensitivity to **Gaviscon Peppermint Tablets** or any of the ingredients.

Phenylketonuria

**WARNINGS AND SPECIAL PRECAUTIONS:**

Sodium: Each 500 mg dose contains 123,0 mg (5,3 mmol) sodium. 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.

Calcium: Each 500 mg dose contains 160 mg (1,6 mmol) calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Sodium bicarbonate should be administered with caution in patients with congestive cardiac failure, renal impairment, cirrhosis of the liver, hypertension and to patients receiving corticosteroids, patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

Prolonged use of **Gaviscon Peppermint Tablets** 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 reports of the milk-alkali syndrome associated with calcium carbonate.

Due to its aspartame content **Gaviscon Peppermint Tablets** should not be given to patients with phenylketonuria (See **CONTRA INDICATIONS**).

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

**Effects on ability to drive and use machines:**

**Gaviscon Peppermint Tablets** has no or negligible influence on the ability to drive and use machines.

**INTERACTIONS:**

**Gaviscon Peppermint Tablets** may interfere with absorption of some medicines.

Interactions can be avoided by giving **Gaviscon Peppermint Tablets** and any other medicines two to three hours apart, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, biphosphonates and estramustine. (See also **WARNINGS AND SPECIAL PRECAUTIONS).**

**HUMAN REPRODUCTION:**

**Pregnancy:**

**Gaviscon Peppermint Tablets** is indicated for heartburn, including heartburn of pregnancy.

**Lactation:**

**Gaviscon Peppermint Tablets** can be used during breastfeeding.

**DOSAGE AND DIRECTIONS FOR USE:**

ORAL ADMINISTRATION WITHOUT WATER.

**Adults and children over 12 years**:

Two to four tablets after meals and at bedtime.

**Children under 12 years**:

Not recommended.

**Elderly**: The same dose as indicated for adults.

Renal insufficiency: Caution if highly restricted salt diet is necessary. (See **WARNINGS AND SPECIAL PRECAUTIONS)**

Tablets should be chewed thoroughly. Tablets should not be swallowed whole.

If symptoms of gastro-oesophageal reflux do not improve within seven days, the clinical situation should be reviewed by a medical practitioner.

**SIDE-EFFECTS:**

**Immune System Disorders:**

Not known: anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.

**Respiratory, Thoracic and Mediastinal Disorders:**

Not known: Respiratory effects such as bronchospasm.

**Gastrointestinal disorders**:

Less Frequent: Stomach cramps, flatulence, constipation

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

The patient may notice abdominal distension. Treatment is supportive and symptomatic.

**IDENTIFICATION:**

A flat circular tablet with bevelled edges, off-white to cream slightly mottled finish with sword and circle on the observe and “G 250” on the reverse, and an odour of peppermint.

**PRESENTATION:**

Cartons containing 8, 16, 24 and 48 tablets comprising of unprinted glass-clear, thermoformable of uPVC/PE/PVDC with aluminium foil lidding.

**STORAGE INSTRUCTIONS:**

Store at or below 25°C

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

A38/11.10/0446

**NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

**DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION :**

Date on the registration certificate: 05 August 2011

Date of the most recently revised patient information leaflet: 14 December 2019