SCHEDULING STATUS:

S0

PROPRIETARY NAMEAND DOSAGE FORM:

Gaviscon Double Action Tablets

COMPOSITION:

Each tablet contains:

Sodium alginate 250 mg

Sodium bicarbonate 106,50 mg

Calcium carbonate 187,50 mg

Other ingredients – mannitol, macrogol 20,000, copovidone, magnesium stearate, coolmint flavour, carmoisine lake and xylitol.

Contains Sweetener (acesulfame k 5,863 mg and aspartame 5,863 mg per tablet)

PHARMACOLOGICAL CLASSIFICATION:

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

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Alginate reacts with gastric acid to form a viscous gel, having a near neutral pH, which floats on the stomach contents impeding gastro-oesophageal reflux. In severe cases the raft may be refluxed into the oesophagus exerting a demulcent effect.

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.

INDICATIONS:

Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion.

CONTRA-INDICATIONS:

Known hypersensitivity to any of the ingredients.

Phenylketonuria

WARNINGS AND SPECIAL PRECAUTIONS

The four tablets dose contains 221.5mg (9.64 mmol) sodium. This should be taken into account when a restricted salt diet is recommended, e.g. in some cases of congestive cardiac failure and renal impairment. Sodium bicarbonate should be administered with caution in patients with congestive heart failure, renal impairment, cirrhosis of the liver, hypertension and to patients receiving corticosteroids, patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

The four tablet dose also contains 300 mg (7.5 mmol) calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing calculus. Prolonged use of Gaviscon Plus 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 Double Action Tablets should not be given

to patients with phenylketonuria.

There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

Prolonged use of Gaviscon Double Action Tablets should be avoided.

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

As with other antacid products, taking this product can mask the symptoms of other more serious, underlying medical conditions.

Effects on ability to drive and use machines

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

INTERACTIONS:

Gaviscon Double Action Tablets may interfere with absorption of some medicines.

A time interval of 2 hours should be considered between Gaviscon Double Action Tablets intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

HUMAN REPRODUCTION:

Pregnancy:

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

Lactation:

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

Fertility:

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

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: No modifications necessary for this age group.age group

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:

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

Gastrointestinal disorders: Uncommon: Stomach cramps, flatulence, constipation

Immune System Disorders: Not known: Anaphylactic reaction, anaphylactoid reaction. Hypersensitivity such as urticaria, bronchospasm

Respiratory, Thoracic and Mediastinal Disorders: Not known: Respiratory effects such as Bronchospasm

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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

IDENTIFICATION:

A flat circular, bi-layered tablet with bevelled edges, pink and slightly mottled with sword and circle on the obverse and white with “GDA250” on the reverse, and an odour of mint.

PRESENTATION:

Cartons containing 8 and 24 tablets in blisters with aluminium foil lidding or packed in a turquoise coloured, polypropylene container with flip-top lid containing 12 tablets.

STORAGE INSTRUCTIONS:

Blister – store at below 30˚C. Store in carton until required for use.

Flip-top- store at or below 25˚C. Use within 3 months of opening.

Protect from moisture.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

42/11.10/0263

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: 14 September 2012

Date of the most recently revised patient information leaflet: 20 December 2019