IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0979/015/007
Case No: 2032524

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Reckitt Benckiser Ireland Ltd

7 Riverwalk, **Citywest Business Campus**, **Dublin 24**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Gaviscon 500mg Lemon Chewable Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **06/02/2007** until **21/12/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon 500 mg Lemon Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains sodium alginate 500 mg, sodium hydrogen carbonate 267 mg and calcium carbonate 160 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
An off-white to cream, slightly mottled tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis.

4.2 Posology and method of administration

For oral use, after being thoroughly chewed.

Adults and children 12 years and over: One to two tablets after meals and at bedtime.

Elderly: No dose modifications necessary for this age group.

4.3 Contraindications

This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

The sodium content of a two-tablet dose is 246 mg (10.6 mmol). 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.

Each two-tablet dose contains 320 mg (3.2 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

Due to its aspartame content this medicinal product should not be given to patients with phenylketonuria.

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

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

Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the presence of calcium carbonate 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 H_2-antihistaminics tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroxine, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine and diphosphonates.

4.6 Pregnancy and lactation

Open controlled studies in 281 pregnant women did not demonstrate any significant adverse effects of Gaviscon on the course of pregnancy or on the health of the foetus/new-born child. Based on this and previous experience the medicinal product may be used during pregnancy and lactation. Nevertheless, taking into account the presence of calcium carbonate (see Section 5.3) it is recommended to limit the treatment duration as much as possible.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Very rarely (<1/10,000) patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions.

4.9 Overdose

In the event of overdose symptomatic treatment should be given. The patient may notice abdominal distension.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) ATC code: A02BX.

On ingestion the medicinal product 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 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.

5.2 Pharmacokinetic properties

The mechanism of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

There is limited evidence in some reports in animals of delay in calcification of foetal skeleton/bone abnormalities relating to calcium carbonate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lemon flavour no. 1
Macrogol 20,000
Mannitol (E421)
Aspartame (E951)
Magnesium stearate
Copovidone
Acesulfame potassium (E950)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

White, rigid, injection-moulded, polypropylene cylindrical container with snap-bead neck finish packed into cartons.

Container containing 20, 40, or 60 tablets.

Unprinted, glass-clear, thermoformable laminate of uPVC/PE/PVdC with aluminium foil lidding blisters packed into cartons.

Blister containing six individually sealed tablets. Pack sizes: 12 and 24 chewable tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited
7 Riverwalk
Citywest Business Campus

Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 979/15/7

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 December 2004

10 DATE OF REVISION OF THE TEXT

February 2007