Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg Alginic acid, 170 mg sodium bicarbonate, 100 mg Aluminium Hydroxide Gel and 25mg Magnesium Trisilicate.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Chewable tablet.

Circular, flat, off-white to cream, bevel-edged tablets, 0.9 inches in diameter with an odour and flavour of peppermint, with ‘Gaviscon’ and sword motif imprinted on both faces.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Gastric reflux, reflux oesophagitis, heartburn, hiatus hernia, heartburn (including heartburn of pregnancy) and similar gastric distress.

4.2 Posology and method of adminstration

Oral.

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

Children 6 to 12 years: One tablet after meals and at bedtime.

4.3 Contraindications

None known.

4.4 Special warnings and special precautions for use

Sodium content of a tablet is 47 mg (2.04 mmol). This should be taken into account when a highly restricted salt diet is required as in some renal and cardiovascular conditions. Products containing aluminium hydroxide should be used with caution in patients with renal dysfunction or hypophosphataemia.

Aluminium hydroxide may cause constipation due to its astringent action; this effect may be balanced by the cathartic effect of the magnesium salts.
Aluminium hydroxide may lead to a phosphate depletion syndrome, particularly in patients on a low phosphate diet, e.g. malnutrition.

Magnesium salts may cause central nervous depression in the presence of renal insufficiency and should not be used in

patients with renal failure.

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium hydroxide may form complexes with certain drugs including those used during pregnancy, e.g. tetracyclines, digoxin and vitamins, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

4.6 Pregnancy and lactation

Alginate has no systemic activity and consequently can be taken during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very rarely patients sensitive to the ingredients may develop allergic manifestations such as urticaria or bronchospasm.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

On ingestion Gaviscon Tablets react 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 mode of action of Gaviscon Tablets is physical and does not depend on absorption into the systemic circulation.

5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol E421
Xylitol
Povidone K30
Magnesium Stearate
Calcium Carbonate
Vanillin
Peppermint oil
Sodium saccharin

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original container.

6.5 Nature and contents of container

Polypropylene container containing 20 tablets. Three tubes in a carton.

6.6 Instructions for use and handling

No special requirements

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited,
Pharmapark,
Chapelizod,
Dublin 20.

8 MARKETING AUTHORISATION NUMBER

PA 979/11/2.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 31st March 2003

10 DATE OF REVISION OF THE TEXT

July 2004