Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon Tablets - Lemon Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg Alginic Acid, 170mg Sodium Bicarbonate, 100mg 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 with a sword logo on each face and an odour of lemon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Gastric reflux, reflux oesophagitis, heartburn, hiatus hernia, flatulence associated with gastric reflux and heartburn of pregnancy. All cases of epigastric and retrosternal distress where the underlying cause is gastric reflux. Treatment of regurgitation.

4.2 Posology and method of adminstration

For oral administration, after being thoroughly chewed.

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

Elderly: No dose modification is required in this age group.

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

Children 2 to 6 years: Should be given only on medical advice. Dose - one tablet after meals and at bedtime.

Infants: Not recommended.

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.

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 in 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 reacts 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 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

Lemon flavour
Sodium saccharin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Two 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 with a plastic snap on lid containing 20 tablets. Three containers 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 979/11/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 2nd October 2003

10 DATE OF REVISION OF THE TEXT

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