Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gaviscon 250 Lemon Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 250 mg alginic acid (Ph. Eur.), 85 mg sodium bicarbonate (Ph. Eur.), 50 mg dried aluminium hydroxide (Ph. Eur.) and 12.5 mg magnesium trisilicate (Ph. Eur.).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet.
Circular matt, off-white to cream chewable tablet, with a lemon odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Relief of heartburn and indigestion.

4.2 Posology and method of adminstration

For oral administration, after being thoroughly chewed. The dose can be rinsed down with a quantity of water.

Adults and children over 12 years: Two tablets as required.

Children under 12 years: Not recommended.

4.3 Contraindications

None known.

4.4 Special warnings and special precautions for use

Sodium content of a tablet is 23.5 mg (1.02 mmol). This may be of importance when a highly restricted salt diet is required as in some renal and cardiovascular conditions.

Aluminium hydroxide may lead to a phosphate depletion syndrome, particularly in patients on a low phosphate diet, e.g. malnutrition.

Aluminium may cause constipation due to its astringent action; this effect may be balanced by the cathartic effect of the magnesium salts.

Magnesium salts may cause central nervous system 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.

4.8 Undesirable effects

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

4.9 Overdose

As the mode of action of Gaviscon is almost entirely physical, overdosage presents virtually no hazard and no ill-effects have been reported. The only likely consequence is abdominal distension which is best treated conservatively.

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
Xylitol
Povidone K30
Magnesium stearate
Calcium carbonate
Sodium saccharin
Lemon flavour no. 2

6.2 Incompatibilities

None known.

6.3 Shelf Life

Two years.

6.4 Special precautions for storage

Do not store above 30°C. Store in a dry place.

6.5 Nature and contents of container

Clear uPVC blisters coated internally with PVdC, thermally sealed to a hard tempered aluminium foil lid and containing 8 tablets. Three foils contained in a cardboard outer carton.

6.6 Instructions for use and handling

No special instructions.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 979/11/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd January 1996
Date of last renewal: 3rd January 2001

10 DATE OF REVISION OF THE TEXT

March 2001