Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Asilone Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Light magnesium oxide 70 mg/5 ml
Dried aluminium hydroxide 420 mg/5ml
Activated dimeticone 135 mg/5ml

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

A white mobile suspension with the taste and odour of peppermint and aniseed.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Antiflatulent and antacid; for the relief of dyspeptic symptoms of functional or organic origin, including flatulence and associated abdominal distension, heartburn, hiatus hernia, and oesophagitis.

4.2 Posology and method of administration

For oral administration.

Adults including the Elderly

One or two 5ml spoonfuls after meals and at bedtime or when required, up to a maximum of four times daily.

Children

The suspension formulation is not recommended for children under 12 years of age.

4.3 Contraindications

Antacid preparations should not be administered in severe debilitation or renal impairment. Do not use during the first trimester of pregnancy.

4.4 Special warnings and precautions for use

Asilone is not recommended in flatulent abdominal distention possibly related to intestinal obstruction.

If symptoms persist consult your doctor.

Not suitable for children under 12 years of age.

Keep all medicines out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may interfere with the absorption of tetracyclines, rifampicin, warfarin and digoxin if given concomitantly.

Antacids should preferably not be taken at the same time as other drugs since they may impair absorption. Antacids may also damage enteric coating designed to prevent dissolution in the stomach.

4.6 Pregnancy and lactation

Antacid preparations are not recommended during the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Aluminium salts may cause constipation and magnesium salts diarrhoea. However, such bowel disturbances are rare with the formulation of Asilone.

4.9 Overdose

No cases of overdosage have been reported with Asilone. The components of Asilone are not expected to cause specific local or systemic toxicity even in acute overdosage in healthy individuals. No special treatment, but symptomatic management only if indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredients possess Antacid and Antiflatulent properties which are long established; their actions in a wide variety of gastro-intestinal disorders are well recognised in standard texts. Light Magnesium Oxide and Aluminium Hydroxide are antacids which increase gastric pH and hence diminish the activity of Pepsin in gastric secretion. In addition, Aluminium Hydroxide has a direct inhibiting effect on Pepsin.

Silicones are useful anti-foaming agents and the addition of 4-8% of finely divided Silicon Dioxide increases the anti-foaming activity of Dimeticones. Dimeticones activated by Silicone Dioxide act by changing the surface tension of gas bubbles, thereby causing them to coalesce.

5.2 Pharmacokinetic properties

No data on pharmacokinetic studies with Asilone are available. The active ingredients, Aluminium Hydroxide and Activated Dimeticone are not normally absorbed. Some Magnesium may be absorbed from Magnesium Oxide in Asilone Suspension, but it is generally rapidly excreted in the urine.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium sorbate
Saccharin sodium
Sorbitol
Flavex peppermint/aniseed flavour L263
Flavex flavour modifer no. 12
Hydrogen peroxide solution
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf Life

Two years.

Use within 28 days of opening.

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and contents of container

Bottles of high density polyethylene in blue, with a white polypropylene cap or a white polyethylene tamper evident cap with a low density polyethylene inner core liner containing either 100 ml, 200 ml, 300 ml or 500 ml.

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

Seton Products Ltd.,
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8 MARKETING AUTHORISATION NUMBER

PA 0618/019/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 October 2002