

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Asilone Antacid Tablets

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated dimeticone 270 mg

Dried aluminium hydroxide 500 mg

*For excipients, see 6.1.*

#### 3 PHARMACEUTICAL FORM

Chewable tablet.

A round, white, flat tablet with bevelled edge, with “Asilone Antacid” embossed on one side.

#### 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 tablets to be chewed or sucked before meals and at bedtime or when required. For heartburn, they should be sucked only.

###### Children

Asilone Antacid Tablets are 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 Antacid Tablets are not recommended in flatulent abdominal distention possibly related to intestinal obstruction.

Asilone Antacid tablets contain 1.1g of Sucrose per tablet and are therefore not recommended for diabetic patients.

Label states:

If symptoms persist consult your doctor.  
Not suitable for children under 12 years of age.  
Keep all medicines out of the 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. 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**

Aluminium Hydroxide is an antacid, which increases gastric pH and hence diminishes 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. The sodium content is low and Asilone Antacid Tablets are therefore particularly suited where there is co-existing hypertension, congestive heart failure, hepatic and/or renal failure.

**5.2 Pharmacokinetic properties**

Active ingredients; Aluminium Hydroxide and Activated Dimethicone are not generally absorbed.

**5.3 Preclinical safety data**

None stated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sucrose  
Sorbitol  
Purified talc  
Levomenthol  
Peppermint oil

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

Five years.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

200 or 250 micron PVC/20 micron aluminium foil blisters in cardboard cartons in packs of 4, 8, 12, 20, 24, 96 or 100 tablets.

### **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.,  
Tubiton House,  
Oldham,  
Lancashire OL1 3HS,  
UK.

## **8 MARKETING AUTHORISATION NUMBER**

PA 0618/019/003

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 11 October 2002