Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Algicon Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	w/v
Magnesium alginate	5.00%
Aluminium hydroxide/Magnesium carbonate coprecipitated dry gel	2.80%
Magnesium Carbonate	3.50%
Potassium Hydrogen Carbonate	1.00%
Precipitated Calcium Carbonate	1.50%

For excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.
A yellow suspension with the odour and taste of lemon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of heartburn associated with gastric reflux, oesophagitis, hiatus hernia, pregnancy and hyperacidity.

4.2 Posology and method of adminstration

To be taken orally.

Adults:	10 to 20 ml or 1 to 2 sachets four times a day or as directed by a physician. The suspension should be taken after meals and at bedtime or as needed.
Children:	Not recommended.
Elderly:	No specific precautions are necessary in normal use.

4.3 Contraindications

None specified.

4.4 Special warnings and special precautions for use

1. Aluminium hydroxide may lead to a phosphate depletion syndrome, particularly in patients on a low phosphate diet e.g. malnutrition.
2. Magnesium salts may cause central nervous depression in the presence of renal insufficiency, and should not be used in patients with renal failure.
3. The physician should be consulted where other medications are being taken, the patient suffers from kidney disease or is under a physician's care.
4. Since this product contains 1 meq. Potassium per 10 ml, use in patients with renal impairment or in those taking potassium sparing diuretics should be cautious and under close supervision.

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium hydroxide may form complexes with certain drugs 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

This product should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

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

4.9 Overdose

In overdose, abdominal distension is the most likely occurrence, appropriate conservative measures should be taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The product contains an alginate combined with an antacid.

The magnesium, on reaction with the gastric contents of the stomach, forms an insoluble gel-like layer above the stomach contents, which impedes reflux and provides a demulcent action.

The aluminium hydroxide/magnesium carbonate and potassium bicarbonate components give the product antacid properties.

5.2 Pharmacokinetic properties

Algicon acts directly on the stomach contents. Systemic absorption is not significant.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol Solution 70/20 (E420)
Xanthan gum
Methylhydroxybenzoate (E218)
Propylhydroxybenzoate (E216)
Calcium saccharin
Natural lemon concentrate
Swiss crème flavour
Peppermint oil
Hydrogen peroxide
Quinoline yellow
Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

Amber glass bottles containing 300 or 500 ml.

White HDPE plastic bottles with polypropylene cap and optional leiraseal containing 100 or 500 ml.

Single dose paper/foil plastic sachets containing 10 ml.

6.6 Instructions for use and handling

Shake bottle to mix contents thoroughly before use.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 468/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th October 1992
Date of last renewal: 20th October 2002

10 DATE OF REVISION OF THE TEXT

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