Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Smecta

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Dioctahedral smectite	3.00	g
Co-dried aluminium hydroxide/magnesium carbonate gel	125.00	mg

3 PHARMACEUTICAL FORM

Smecta is a powder for oral suspension presented in single dose sachets. It is a white greyish to buff coloured powder with an odour of vanilla and liquorice.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of non-specific diarrhoea and stomach upsets.

4.2 Posology and method of administration

Adults and children over 5 years:
The usual dose is one sachet three times daily.

Infants and children aged to 2 to 5 years:
The usual dose is half a sachet three times daily.

To be taken preferably between meals or slightly before a meal.

The content of the sachet may be diluted in half a glass of water or mixed with a semi-liquid food.

In order to obtain a homogeneous suspension pour the powder slowly into the liquid, whilst stirring.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

(i) In view of the presence of a small amount of aluminium hydroxide and magnesium carbonate there is a theoretical risk of phosphate depletion in the case of prolonged treatment using very high doses.
(ii) If diarrhoea is accompanied by high fever consult your doctor.
(iii) If symptoms persist for more than 24 hours consult your doctor.
(iv) Not for use in children under 2 years except on medical advice.
(v) When treating childhood gastro-enteritis attention should be paid to adequate hydration and the need for specific dehydration therapy.

4.5 Interaction with other medicinal products and other forms of interaction

The absorbent properties of the preparation may interfere with the absorption times and/or rates of another substance and it is suggested that all other drugs should be administered separately from Smecta.

4.6 Pregnancy and lactation

No special precaution need to be taken.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

In rare cases constipation may arise or existing constipation may be aggravated.

Treatment can usually be continued after reduction of the dosage.

4.9 Overdose

There is no experience of overdosage. If overdosage occurs, symptomatic management is indicated; there are no specific antidote.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Smecta is a medication characterised by the high level of plastic viscosity (thixotropism) of its suspensions, and hence by good covering power.

Smecta is a mucostabilising agent which becomes incorporated in the mucus, prolonging its existence by forming a physical barrier which isolates the digestive mucosa from the aggressive effects of H^+ ions, organisms within the intestinal lumen, their toxins and irritant substances.

Smecta reduces and buffers gastric hyperacidity without going beyond physiological norms and without inducing rebound acid secretion.

Smecta has absorbent properties which may be explained by the layered structure of the particles. By contrast, the swelling power is very low.

In vitro Smecta activates contact coagulation factors. Thus it may be considered to have haemostatic properties on digestive tract ulcers.

Smecta is radio-transparent, does not colour the stools and at usual doses does not alter physiological intestinal transit time.

5.2 Pharmacokinetic properties

The co-dried gel forms a complex which acts locally on the gastro-intestinal tract. Under the physiological conditions of the gastro-intestinal tract smectite is chemically inert and is not absorbed.

The aluminium component of dioctahedral smectite is part of the crystalline structure and is unavailable at the pH conditions found in the gastro-intestinal tract. Some magnesium may be absorbed but is usually excreted rapidly in the

urine.

5.3 Preclinical safety data

The active ingredients are well known and do not represent a safety hazard.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose
Saccharin sodium
Dry liquorice extract
Vanillin

6.2 Incompatibilities

None known.

6.3 Shelf Life

Three year.

6.4 Special precautions for storage

Do not store above 25°C.
To be stored in a dry place.

6.5 Nature and contents of container

Single dose sachets composed of Kraft paper, polyvinylidine chloride and polyethylene. Each sachet contains a nominal 3.9 g or powder.

Carton of 30 sachets
Carton of 60 sachets

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

None.

7 MARKETING AUTHORISATION HOLDER

Beaufour Ipsen Pharma
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75 781 Paris Cedex 16
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8 MARKETING AUTHORISATION NUMBER

PA 1003/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 January 1985

Date of last renewal: 31 January 2000