Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Senokot 7.5 mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The syrup contains an aqueous extract of standardized senna pods equivalent to a total sennoside content (calculated as sennoside B) of 7.5 mg per 5 ml.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Syrup
Brown liquid with odour of prunes.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

500 ml (dispensing pack)
In the management of occasional constipation.

100 ml pack
As a laxative for the relief of occasional or non-persistent constipation.

4.2 Posology and method of administration

Senokot Syrup is for oral administration.

500 ml (dispensing pack)

Adults, including the elderly and children over 12: Two to four 5 ml spoonfuls in 24 hours.

Not to be given to children under 12 years except on medical advice.
Where administration to children is necessary, the recommended dose is as follows:

Children over 6 years: One to two 5 ml spoonfuls in 24 hours.

Children aged 2 to 6 years: Half to one 5 ml spoonful in 24 hours.

Senokot should be taken as a single dose at bedtime by adults and in the morning by children.

New users should start the lowest dose and increase it, if necessary, by one half of the initial dose each day. Once regularity has been regained the dosage should be gradually reduced and stopped.

If no bowel action has occurred after three days progressively increased dosage, a medical examination should be considered.

100 ml pack

Adults, including the elderly and children over 12: Two 5 ml spoonfuls taken at night.

Not to be given to children under 12 years except on medical advice.
Where administration to children is necessary, the recommended dose is as follows:

Children over 6 years: One 5 ml spoonful taken in the morning.

Children aged 2-6 years: Half to one 5 ml spoonful, taken in the morning.

4.3 Contraindications

Senokot Syrup should not be given when any undiagnosed acute or persistent abdominal symptoms are present.

4.4 Special warnings and precautions for use

Senokot Syrup should not be used in diabetic patients, but should be replaced with tablets which have negligible sugar content.

Not to be given to children except on medical advice.

If there is no bowel movement after three days consult a doctor.

If laxatives are needed every day or abdominal pain persists consult a doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

This product should not be used during pregnancy and lactation unless considered essential by the physician. There is some evidence for the safety of senna in human pregnancy and it has been in use for many years without apparent ill-consequence. Anthraquinones are excreted into breast milk, but clinical studies have shown that breast-fed infants of mothers taking Senokot did not show any side-effects to the drug.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Temporary mild griping may occur during adjustment of the dosage.

4.9 Overdose

Where diarrhoea is severe conservative measures are usually sufficient: generous amounts of fluid, especially fruit drinks, should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Anthraquinone laxative, the active principles of which are release into the colon by the action of colonic bacteria. Senna acts in 8-12 hours.

5.2 Pharmacokinetic properties

The action of the sennosides is colon specific and does not depend upon systemic absorption.

5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Ethanol
Anti-foam (M30) emulsion
Prune flavour
Sodium hydroxide
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 20°C. Keep the container tightly closed.

6.5 Nature and contents of container

Type II glass bottle with a polypropylene cap with a polyethylene tamper-evident band with an expanded polyethylene wad containing 100 or 50 ml syrup.

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

Reckitt Benckiser Ireland Limited
Pharmapark
Chapelizod
Dublin 20

8 MARKETING AUTHORISATION NUMBER

PA 979/16/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 September 1986

Date of last renewal: 04 September 2001

10 DATE OF REVISION OF THE TEXT

December 2005