Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Senokot 7.5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains standardised powdered senna pods equivalent to 7.5mg total sennosides calculated as Sennoside B.

Excipient: contains Lactose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from the UK:
Circular, biconvex, greenish brown tablets, with one face imprinted with “S” and plain on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a laxative in the treatment of occasional constipation.

4.2 Posology and method of administration

Senokot Tablets are for oral administration.

Adults only: 2-4 tablets in 24 hours, to be taken at night.

Not to be given to children except on medical advice.

4.3 Contraindications

Senokot Tablets should not be given to patients with symptoms of appendicitis, intestinal obstruction, inflammatory bowel disease, including ulcerative colitis, or abdominal pain of unknown origin.

4.4 Special warnings and precautions for use

If symptoms persist, consult your doctor.

Prolonged continuous use is not recommended.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

The product should not be used during pregnancy and lactation unless considered essential by the physician.

Anthraquinones are excreted into the milk or nursing mothers but clinical studies have shown that breastfed infants of mothers taking Senokot in the puerperium 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

Senna may give rise to griping abdominal pain.

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

The sugar moiety of the sennosides is removed by bacteria in the large intestine releasing the active anthrone fraction. This stimulates peristalsis via the submucosal and myenteric nerve plexuses. 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 have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Phosphate
Maize Starch
Lactose
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package to protect from moisture.

6.5 Nature and contents of container

Blister packs of 20, 60 or 100 tablets in an over-labelled outer cardboard carton.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

G & A Licensing Ltd.
Ballymurray
Co. Roscommon
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1447/73/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th March 2011

10 DATE OF REVISION OF THE TEXT

April 2013