Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Senokot 7.5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains 154 mg *Cassia senna* L. (*C. acutifolia* Delile) (Senna pods, Alexandrian)/Cassia angustifolia Vahl (Senna pods Tinnevely), standardised to contain 7.5 mg total sennosides per tablet, calculated as sennoside B.
Excipient: Contains Lactose Monohydrate 15.82mg
For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Circular, biconvex, greenish-brown tablets, with a diameter of 11/32 inch, one face imprinted with 'S'.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short-term relief of occasional constipation.

4.2 Posology and method of administration

Posology
Adults, including the elderly and children over aged 12 years and over: Swallow 2 tablets at night.

Children 12 years and under: Contraindicated in children under 12 years.

Use for more than 1 week requires medical supervision. If the symptoms persist or worsen during the use of the medicinal product, a doctor should be consulted (see section 4.4).

Method of administration
For oral administration.

4.3 Contraindications

Hypersensitivity to senna or to any of the excipients listed in section 6.1

Concomitantly with other laxative agents.

Senokot Tablets should not be given to patients with symptoms of appendicitis, intestinal obstruction, stenosis, atony, inflammatory bowel disease (e.g. Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion

Children under 12 years of age.

4.4 Special warnings and precautions for use

Patients should be advised to consult their doctor if senna is needed every day, or abdominal pain persists or worsens.

Patients should be advised to consult their doctor if there are no bowel movements after three days if senna is needed every day and the cause of the constipation should be investigated. Long-term use of laxatives should be avoided.

Senna should not be taken by patients suffering from faecal impaction and undiagnosed, acute or persistent gastro-intestinal complaints, e.g. abdominal pain, nausea and vomiting, unless advised by a doctor, because these symptoms can be signs of potential or existing intestinal blockage (ileus).

If stimulant laxatives are taken for longer than a brief period of treatment, this may lead to impaired function of the intestine and dependence on laxatives. Senna pods preparations should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents.

Prolonged and excessive use may lead to diarrhoea with excessive loss of water and electrolytes, particularly potassium; there is also the possibility of developing an atonic non-functioning colon.

Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and oliguria.

Prolonged and excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

When preparations containing senna leaf preparations are administered to incontinent adults, pads should be changed more frequently to prevent extended skin contact with faeces.

Patients with kidney disorders should be aware of possible electrolyte imbalance.

Laxatives do not help in long-term weight loss.

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

4.5 Interaction with other medicinal products and other forms of interaction

Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products, with medicinal products, which induce reversion to sinus rhythm (e.g. quinidine) and with medicinal products inducing QT-prolongation.

Concomitant use with other medicinal products inducing hypokalaemia (e.g. diuretics, adrenocorticosteroids and liquorice root) may enhance electrolyte imbalance.

4.6 Fertility, pregnancy and lactation

Pregnancy

The use during pregnancy is contraindicated because of experimental data concerning a genotoxic risk of several anthranoids, e.g., emodin and aloe emodin.

Breast-feeding

The use during lactation is contraindicated because after administration of anthranoids, active metabolites, such as rhein, were excreted in breast milk in small amounts.

Fertility
There are no data on the effects of the product on fertility.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse events which have been associated with senna are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very Common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Very rare

(<1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

SystemOrganClass	Frequency	AdverseEvents
Immune System Disorders	NotKnown	Hypersensitivity[1], hypogammaglobulinaemia
Metabolism and NutritionDisorders	NotKnown	Hypokalaemia[2] , cachexia
Gastrointestinal Disorders	NotKnown	Abdominal pain[3], abdominal spasm, diarrhoea[3],gastrointestinal tract mucosal pigmentation[4]
Skin and Subcutaneous Tissue Disorders	NotKnown	Pruritus, exanthema generalised
Musculoskeletal and Connective Tissue Disorders	NotKnown	Fingerclubbing,tetanyand hypertrophic osteoarthropathy
Renal and Urinary Disorders	NotKnown	Chromaturia[5], albuminuria, haematuria, electrolyte imbalance

Description of Selected Adverse Reactions
[1] Including pruritus, urticaria, local or generalised exanthema, asthma
[2]Prolonged use of laxatives resulting in diarrhoea and subsequently hypokalaemia.

[3]Particular in patients with irritable colon.

[4]Chronic use may cause pigmentation of the intestinal mucosa (pseudomelanosis coli), which usually recedes with the patients stops taking the preparation.

[5]Yellow or red-brown (pH dependent) discolouration of urine by metabolites, which is not clinically significant, may occur during the treatment.

Reporting of Suspected Adverse Events
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +35 1 6762517;
Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

The major symptoms of overdose are griping pain and severe diarrhoea with consequent losses of fluid and electrolytes. Diarrhoea may especially cause potassium depletion, which may lead to cardiac disorders and muscular asthenia, particularly where cardiac glycosides, diuretics, adrenocorticorticosteroids or liquorice root are being taken at the same time.

Chronic ingested overdoses of anthranoid containing medicinal products may lead to toxic hepatitis.

Management
Treatment should be supportive with generous amounts of fluid, especially fruit drinks, should be given. Electrolytes, especially potassium, should be monitored.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: senna glycosides; ATC Code: A06AB06

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.

1,8-dihydroxyanthracene derivatives possess a laxative effect. The β-O- linked glycosides (sennosides) are not absorbed in the upper gut; they are converted by bacteria of the large intestine into the active metabolite (rhein anthrone).

There are two different mechanisms of action:
1.Stimulation of the motility of the large intestine resulting in accelerated colonic transit.
2.Influence on the secretion processes by two concomitant mechanisms viz. inhibition of absorption of water and electrolytes (Na+, CL-) into the colonic epithelial cells (antiabsorptive effect) and increase of the leakiness of the tight junctions and stimulation of secretion of water and electrolytes into the lumen of the colon (secretagogue effect) resulting in enhanced concentrations of fluid and electrolytes in the lumen of the colon.

Defaecation takes places after a delay of 8-12 hours due to the time taken for transport to the colon and metabolisation into the active compound.

5.2 Pharmacokinetic properties

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

The β-O-linked glycosides (sennosides) are neither absorbed in the upper gut nor split by human digestive enzymes. They are converted by bacteria of the large intestine into the active metabolite (rhein anthrone). Aglyca are absorbed in the upper gut. Animal experiments with radio-labelled rhein anthrone administered directly into the caecum demonstrated absorption <10%. In contact with oxygen, rhein anthrone is oxidised into the rhein and sennidins, which can be found in the blood, mainly in the form of glucuronides and suphates. After oral administration of sennosides, 3-6% of the metabolites are excreted in urine; some are excreted in bile. Most of the sennosdies (ca. 90%) are excreted in faeces as polymers (polyquinones) together with 2 – 6% of unchanged sennosides, sennidins, rhein anthrone and rhein. In human pharmacokinetic studies with senna pods powder (20 mg sennosides), administered orally for 7 days, a maximum concentration of 100ng rhein/ml was found in the blood. An accumulation of rhein was not observed. Active metabolites, e.g. rhein, pass in small amounts into breast milk. Animal experiments demonstrated that placental passage of rhein is low.

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 monohydrate
Magnesium stearate

6.2 Incompatibilities

Not known.

6.3 Shelf life

3 years for tablets packed in UPVC/PVdC aluminium foil blisters.
5 years for tablets packed in polypropylene containers with snap fit lids.

6.4 Special precautions for storage

Blisters: Store below 25°C. Store in the original package.
Polypropylene containers: Store below 30°C. Store in the original package.

6.5 Nature and contents of container

UPVC/PVdC aluminium foil blisters containing 6, 20, 60 or 100 tablets.

Polypropylene containers with snap-fit lids containing 500 tablets.

Not all pack sizes may be marketed.

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

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/016/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

August 2022