Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product name: Senokot
Dosage form: Tablet
Strength: Each tablet contains 7,5 mg of Sennoside B

2015 03 CCDS Updates amendment

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

Senokot ® Tablets

COMPOSITION

Active ingredients:

Each tablet contains 7,5 mg of Sennoside B

Inactive ingredients:

Calcium phosphate**,** lactose monohydrate, magnesium stearate and maize starch.

Contains sugar: lactose monohydrate 15,82 mg per tablet

PHARMACOLOGICAL CLASSIFICATION

A 11.5 Laxatives

PHARMACOLOGICAL ACTION

Pharmacodynamic Properties:

Sennosides A and B are anthraquinone glycosides. These are hydrolysed by bacterial action in the colon to give free anthraquinones which promote bowel movement by increasing colonic peristalsis.

Pharmacokinetic Properties:

Senokot acts within 6-12 hours.

INDICATIONS

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For the relief of occasional constipation.

CONTRAINDICATIONS

Senokot is contraindicated:

- in patients with hypersensitivity to sennosides or any of the ingredients of **Senokot**.
- in patients with intestinal obstruction or undiagnosed abdominal symptoms, acute or persistent gastrointestinal complaints, and stenosis, atony, appendicitis, inflammatory bowel diseases (e.g. Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water or electrolyte depletion.
- in children under the age of 12.
- when used concomitantly with other laxatives.

WARNINGS AND SPECIAL PRECAUTIONS

If you have noticed a sudden change in the bowel habits that has persisted for a period greater than 2 weeks, consult a doctor before using the laxative. This medicine should not be taken by patients suffering from faecal impaction and undiagnosed, acute or persistent gastrointestinal complaints, e.g. abdominal pain, nausea or vomiting unless advised by a doctor, because these symptoms can be signs of potential or existing intestinal blockage (ileus).

Frequent or prolonged use of this preparation may result in dependence on laxatives and loss of normal bowel function. Do not use for period longer than one week, unless directed by a doctor. Rectal bleeding or failure to have a bowel movement after three days of use of **Senokot** may indicate a serious condition. Discontinue use and consult a doctor.

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If **Senokot** is needed every day the cause of the constipation should be investigated.

Senna pods preparations, such as **Senokot**, should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming medicines.

Prolonged and excessive use of **Senokot** may lead to diarrhoea with excessive loss of water and electrolytes, particularly potassium leading to hypokalaemia. 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.

Care should be taken in patients with inflammatory bowel disease.

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

Effects on ability to drive and use machines:

No known effects.

Excipients:

Senokot contains lactose monohydrate. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **Senokot**.

INTERACTIONS

Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of digoxin and interacts with anti-dysrhythmic medicines, with medicines which induce reversion to sinus rhythm (e.g. quinidine) and with medicines inducing QT prolongation.

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

PREGNANCY AND LACTATION

Pregnancy:

There are no reports of undesirable or damaging effects during pregnancy and on the foetus when used at the recommended dosage schedule.

However, as a consequence of experimental data concerning a genotoxic risk of several anthranoids such as **Senokot**, e.g. emodin and aloe-emodin, use is not recommended during pregnancy.

Lactation:

Use during breastfeeding is not recommended as there are insufficient data on the excretion of metabolites in breast milk.

Small amounts of active metabolites (rhein) are excreted in breast milk.

DOSAGE AND DIRECTIONS FOR USE

The correct dosage of **Senokot** is the smallest required to produce a comfortable, soft-formed motion. It varies between individuals, but is generally found within the following range:

Adults and children over 12 years: 2 – 4 tablets once a day.

Not recommended for use in children under the age of 12 years. New users should start with the lowest dose and, if necessary, increase it by half the initial dose each day until a comfortable formed motion is produced. If no bowel action has occurred after three days' progressively increased dosage, discontinue use and consult a doctor.

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SIDE EFFECTS

Adverse events which have been associated with senna are given below and classified by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 and < 1/10); uncommon (≥ 1/1 000 and <1/100); rare (≥ 1/10 000 and <1/1 000); very rare (> 1/10 000); not known (cannot be estimated from available data).

Immune system disorders:

Not known: Hypersensitivity, urticaria and hypogammaglobulinaemia

Respiratory, thoracic and mediastinal disorders:

Not known: Asthma

Metabolism and nutrition disorders:

Not known: Hypokalaemia and cachexia

Gastrointestinal disorders:

Not known: Abdominal pain such as cramps and colic, diarrhoea and gastrointestinal tract mucosal pigmentation

Skin and subcutaneous tissue disorders:

Not known: Pruritus and exanthema generalised

Musculoskeletal and connective tissue disorders:

Not known: Finger clubbing, tetany and hypertrophic osteoarthropathy

Renal and urinary disorders:

Not known: Chromaturia (discolouration of urine may occur and may interfere with diagnostic tests)

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms of overdose:

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The major symptoms of overdose are griping pain and severe diarrhoea with consequent losses of fluid and electrolytes.

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

Treatment of overdose:

Treatment is symptomatic and supportive with generous amounts of fluid. Electrolytes, especially potassium, should be monitored.

IDENTIFICATION

A round khaki-coloured, biconvex, straight-edged tablet, with an “S” imprinted on the side and plain on the other side.

PRESENTATION

Aluminium foil/PVC blister of 20, 60 and 100 tablets; securitainers of 200 and 1 000 tablets.

STORAGE INSTRUCTIONS

Protect from moisture and store at or below 25 C in a dry place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

E/11.5/671 (South Africa)

81/11.5/1229 (Zimbabwe)

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NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Reckitt Benckiser Pharmaceuticals (Pty) Ltd.

8 Jet Park Road

Elandsfontein

1601

DATE OF PUBLICATION OF PACKAGE INSERT

Date on the registration certificate: 21 January 1997

Date of most recently revised package insert approved by Council: 25 April 2020