APPROVED PATIENT INFORMATION LEAFLET

Scheduling status

S0

Proprietary name, strength and pharmaceutical form

SENOKOT 7,5 mg Tablets

Read all of this leaflet carefully because it contains important information for you.

SENOKOT is available without a doctor's prescription for you to treat a mild illness. Nevertheless you still need to use **SENOKOT** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **SENOKOT** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

1. What SENOKOT contains

Each tablet contains 7,5 mg of Sennoside B as the active ingredient.

The other ingredients are calcium phosphate, lactose monohydrate, magnesium stearate and maize starch.

Contains sugar: lactose monohydrate 15,82 mg per tablet.

2. What SENOKOT is used for

SENOKOT tablets are used for the relief of occasional constipation.

3. Before you take SENOKOT

Do not take SENOKOT:

- if you are allergic to sennosides or any of the ingredients of **SENOKOT**;
- if you have sharp or persistent stomach pain;
- if your abdomen is tender to touch and hurts or hurts when you move;
- if you have severe dehydration;
- if you are taking other medicines used to treat constipation (laxatives);
- if you are a child under the age of 12.

Take special care with SENOKOT:

- if you notice a sudden change in the bowel movements which has lasted for more than 2 weeks, consult a doctor before using the laxative;
- if you suffer from dry, hard stool, abdomen pain, feeling sick or vomiting unless advised by a doctor;
- if you need to use the medicine for a longer period or frequently, as this 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;
- if you are bleeding from the anus or failure to pass a stool after three days of using **SENOKOT** as this may indicate a serious condition. Stop use and consult a doctor;
- prolonged and excessive use may lead to diarrhoea with resultant excessive loss of water and electrolytes and low potassium levels. There is also the possibility of developing a muscle weakness of the large intestine. Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and infrequent urination;
- if you have a kidney disorder, as use of **SENOKOT** could lead to possible electrolyte imbalance;

Pregnancy and breastfeeding:

The use of **SENOKOT** is not recommended during pregnancy and while breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking **SENOKOT**.

Driving and using machinery:

SENOKOT tablets are not expected to affect the driving or the ability to operate tools or machines.

Taking other medicines with SENOKOT:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

SENOKOT tablets should not be used together with other medicinal products inducing low potassium blood levels (hypokalaemia) such as diuretics (water pills), adrenocorticosteroids (steroids) and liquorice root may enhance electrolyte imbalance.

Hypokalaemia (resulting from long-term laxative abuse) increases the effects of digoxin (a medicine used to treat heart failure) and interacts with anti-dysrhythmics (medicines used to control heart rhythms) for example quinidine and with medicines inducing heartbeat prolongation.

4. How to take SENOKOT

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 movement has occurred after three days of dosage, stop use and consult your doctor.

If you take more SENOKOT than you should:

If you accidentally take too many **SENOKOT** tablets, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take SENOKOT:

If you miss a dose of this medicine, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule. Do not take double dose to make up for the forgotten individual doses.

5. Possible side effects

Like all medicines, **SENOKOT** can have side effects.

Not all side effects reported for **SENOKOT** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SENOKOT**, please consult your health care provider for advice.

If any of the following happens, stop taking Senokot and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- severe itching of the skin or generalised rash,

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SENOKOT**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you

notice any of the following:

- difficulty breathing,

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- abdominal pain such as cramps and colic, diarrhoea, discolouration of moist linings of the mouth,
- finger clubbing, involuntary muscle spasm or contraction, combination of clubbing and swelling of the hand joints, and
- discolouration of urine especially when urine tests are to be performed.

You may experience temporary mild stomach pains when changing dosage. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. Storing and disposing of the medicine

Protect from moisture. Store in a dry and cool place (below or at 25 °C).

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. Presentation

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

8. Identification

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

9. Registration number

E/11.5/671 (South Africa)

81/11.5/1229 (Zimbabwe)

10. Name and address of registration holder

Reckitt Benckiser Pharmaceuticals (Pty) Ltd.

8 Jet Park Road,

Elandsfontein, 1601

11. Date of publication

Date on the registration certificate: 21 January 1997

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