

## Package leaflet: Information for the user

### SEKOKOT 7.5mg TABLETS

Sennosides

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### **What is in this leaflet:**

1. What Senokot 7.5mg Tablets are and what they are used for
2. What you need to know before taking Senokot 7.5mg Tablets
3. How to take Senokot 7.5mg Tablets
4. Possible side effects
5. How to store Senokot 7.5mg Tablets
6. Contents of the pack and other information

#### **1. What Senokot 7.5mg Tablets are and what they are used for**

Senokot is a laxative used for the short-term relief of occasional constipation.

#### **2. What you need to know before taking Senokot 7.5mg Tablets**

##### **Do not take if you:**

- are allergic to senna or any of the other ingredients of this medicine (listed in section 6)
- have blockage or narrowing of the gastro-intestinal tract or bowel (ileus, intestinal obstruction or stenosis)
- have paralysis or a lack of muscle tone in the bowel (atony)
- have symptoms of appendicitis, inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have severe dehydration
- have already taken a laxative and are still constipated
- are under 12 years of age

##### **Warnings and precautions**

##### **Talk to your doctor, pharmacist or nurse before taking Senokot 7.5mg Tablets if:**

- senna is needed every day, or abdominal pain persists or worsens
- you have no bowel movements after three days
- you need senna every day and the cause of constipation should be investigated. Long-term use of laxatives should be avoided
- you suffer from kidney disorders
- have faecal impaction or rectal bleeding for which you don't know the cause, or blood in your stools
- have had a sudden change in bowel habit that has lasted for more than 2 weeks
- have persistent or undiagnosed abdominal complaints e.g. pain, nausea, or vomiting

Laxatives do not help in long term weight loss

#### **Other medicines and Senokot 7.5mg Tablets**

Talk to your doctor or pharmacist if you are taking medicines for a heart condition or heart rhythm problems (e.g. cardiac glycosides, antiarrhythmic medicines e.g. quinidine) including medicines which may cause changes to your heart beat (QT prolongation), diuretics (medicine to help you pass urine), adrenocorticosteroids

or liquorice root preparations.

You should consult your doctor or pharmacist for advice if you are taking or have recently taken any other medicines, including those listed above and any medicines obtained without prescription.

#### **Pregnancy, breast-feeding and fertility**

Do not use this product if you are pregnant or breast-feeding.

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

##### **Excipient Warnings**

Senokot 7.5mg Tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

It is recommended to use changes in diet and bulk forming medicines to control constipation before using this medicine.

### 3. How to take Senokot 7.5mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

#### **Adults, including the elderly and children aged 12 years and over:**

The recommended dose is to swallow 2-4 tablets at night.

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

**Do not exceed the stated dose.**

#### **Method of administration:**

Senokot 7.5mg Tablets are for oral administration.

Normally it is sufficient to take this medicine product up to two to three times a week. Use for more than 1 week requires medical supervision.

Tell a doctor, pharmacist or nurse if:

- the symptoms worsen, or persist during the use of the medicinal product.
- there is no bowel movement within 3 days of use
- you need to take laxatives every day or if abdominal pain persists.

#### **If you take more than you should:**

Consult your doctor and take this leaflet with you.

It may be harmful to take too much of this medicine or take it for too long. This is because it may lead to:

- A 'lazy bowel', where the muscle in the bowel becomes too relaxed. This means that bowel emptying happens less often. This can lead to long-term constipation.
- Imbalance of fluids and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.
- Low levels of potassium in the blood (called hypokalaemia). This can make you tired, dizzy, make your muscles weak and cause an uneven heart-beat.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean that you cannot pass enough urine.

**If you forget to take a dose:** If you miss a dose, take your next dose at the usual time. Do not take two doses at the same time to make up for a missed dose.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following:

- abdominal pain, spasms and diarrhoea, in particular these effects may be experienced by patients with irritable colon. In these cases, a reduction in dose may be necessary.
- hypersensitivity (allergic) reactions, hives (skin bumps), skin itchiness or local or more widespread rash, or asthma.
- can make you more likely to catch infections.
- chronic use may lead to albuminuria and haematuria which is albumin or red blood cells in the urine.
- yellow or red-brown discolouration of urine may occur, which is harmless
- prolonged use may lead to an electrolyte imbalance
- chronic use may cause pigmentation of the gastrointestinal tract which usually recedes when the product is no longer taken.
- low potassium levels in the blood leading to muscle weakness and/or cramps
- severe weight loss
- changes in the shape of the finger and fingernail, muscular spasms and inflammation of bones and joints

The frequency is not known.

In patients at risk from or suffering from fluid loss where dehydration may be harmful (e.g. kidney disorders, elderly patients), patients should be aware of symptoms of electrolyte imbalance, particularly chronic diarrhoea. Additional symptoms of electrolyte imbalance may include, but are not limited to; tiredness, fatigue, dizziness, abdominal pain, nausea and vomiting. If you experience these symptoms, Senokot 7.5mg Tablets should be discontinued and only be restarted under medical supervision.

**Reporting of side effects:** If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report side effects directly via HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Senokot 7.5mg Tablets

**Keep this medicine out of the sight and reach of children.**

**Blister:** Store below 25°C. Store in the original package.

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

Do not use this medicine after the expiry date which is stated on the label and carton (EXP month/year). This refers to the last day of the month.

#### **6. Contents of the pack and other information**

What Senokot 7.5mg Tablets contains:

Each tablet contains Cassia senna L. (*C. acutifolia* Delile) (Senna pods, Alexandrian)/Cassia angustifolia Vahl (Senna pods, Tinnevely), standardised to contain 7.5mg total sennosides per tablet, calculated as sennoside B. This medicine also contains: calcium phosphate, maize starch, magnesium stearate and lactose monohydrate.

#### **What Senokot 7.5mg Tablets looks like and contents of the pack:**

Senokot 7.5mg Tablets are circular, biconvex, greenish brown tablets, with a diameter of 11/32 inch, one face imprinted with "S". They are available in blister packs in pack sizes of 6, 20, 60, or 100 tablets and in containers in pack sizes of 500 tablets. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturers**

Marketing Authorisation Holder: Reckitt Benckiser Ireland, Ltd., Citywest Business Campus, Dublin 24

Manufacturers: Reckitt Benckiser Healthcare (UK) Limited, Hull, HU8 7DS, UK and RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

For further information please call (01) 630 5429

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Leaflet was last revised upon approval

Senokot is a trademark.