

PACKAGE LEAFLET: INFORMATION FOR THE USER

Senokot 7.5mg Tablets (sennosides)

Your medicine is available using the above name but will be referred to as Senokot Tablets throughout this leaflet.

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

What is in this leaflet:

- What Senokot Tablets are and what they are used for
- What you need to know before taking Senokot Tablets
- How to take Senokot Tablets
- Possible side effects
- How to store Senokot Tablets
- Contents of the pack and other information

1. What Senokot Tablets are and what they are used for

Senokot Tablets are a laxative used in the treatment of occasional constipation.

2. What you need to know before taking Senokot 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 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.

Excipient warnings

Senokot Tablets contain lactose. 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.

Other medicines and Senokot 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 a prescription.

Pregnancy, Breast-feeding and Fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as use in pregnancy and breast-feeding is not recommended.

3. How to take Senokot 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 over 12 only:

The recommended dose is 2-4 tablets in 24 hours, to be taken at night.

Children 12 years and under: Not suitable for use in children under 12 years.

Do not exceed the stated dose.

Use for 1-2 weeks requires medical supervision. If the symptoms persist or worsen during the use of the medicinal product, a doctor should be consulted.

Method of administration:

Senokot Tablets are for oral administration. Normally it is sufficient to take this medicinal product up to two to three times a week. Use for more than 1-2 weeks 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
- 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.

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 also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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

5. How to store Senokot Tablets

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

Store in the original package to protect from moisture.
Store below 25°C.

Do not use this medicine after the expiry date which is stated on the label & carton (EXP day/month/year).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Senokot Tablets contain

The active ingredient is senna.
Each tablet contains standardised powdered senna equivalent to 7.5mg total sennosides calculated as Sennoside B.
This medicine also contains: calcium phosphate, maize starch, lactose & magnesium stearate.

What Senokot Tablets look like and contents of the pack

Senokot tablets are circular, biconvex, greenish brown tablets, imprinted with "S" on one side and plain on the other.

Your medicine is available in blister packs of 20, 60 or 100 tablets. Not all pack sizes may be marketed.

Manufacturer

Manufactured by: Reckitt Benckiser Healthcare (UK) Ltd., Hull, HU8 7DS, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business
Park, Santry, Dublin 9.

PPA No: 1151/113/1

Leaflet revision and issue date (Ref): 11.10.17

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Blind or partially sighted?
Is this leaflet hard to see or
read?

Call +44 (0) 1302 365000
(Regulatory)

Please be ready to give the
following information:

Product name:

Senokot 7.5mg Tablets

Reference No: 1151/113/1