

PATIENT INFORMATION LEAFLET

Senokot 7.5mg/5ml Syrup

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

This medicine is available without prescription. However, you still need to take Senokot Syrup carefully to get the best results from it.

- 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 any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please speak to your doctor or pharmacist Immediately.

In this leaflet:

1. What Senokot Syrup 7.5mg/5ml Syrup is and what it is used for
2. Before taking Senokot Syrup 7.5mg/5ml Syrup
3. How to take Senokot Syrup 7.5mg/5ml Syrup
4. Possible side effects
5. How to store Senokot Syrup 7.5mg/5ml Syrup
6. Further Information

1. What is Senokot 7.5mg/5ml Syrup and what is it used for?

Senokot Syrup 7.5mg/5ml contains calcium sennosides, which work as a laxative for the short term relief of occasional constipation. Constipation is a fairly common and uncomfortable complaint. It usually involves difficult or irregular bowel movements, accompanied by hard, dry motions which can be painful to pass. This medicine does not help with weight loss.

2. Before taking Senokot 7.5mg/5ml Syrup

Do not take Senokot 7.5mg/5ml Syrup if you:

- are allergic to any of the ingredients (for a full list of ingredients, see 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 – decreased muscle contraction)
- have appendicitis, inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- have severe dehydration
- have persistent or undiagnosed abdominal complaints e.g pain, nausea, or vomiting
- have already taken a laxative and are still constipated
- are pregnant or breastfeeding

This medicine is not to be given to children under 12 years of age.

Tell your doctor, pharmacist or nurse if:

- you suffer from kidney disorders
- you have no bowel movement after three days
- laxatives are needed every day or abdominal pain persists.
- you have hereditary intolerance to certain sugars (e.g. fructose intolerance)
- you are taking medicines for a heart condition (e.g. cardiac glycosides, antiarrhythmic medicines e.g. quinidine, medicines inducing QT elongation, diuretics, adrenocorticosteroids (types of steroids) or liquorice root preparations.
- you are suffering from faecal impaction and undiagnosed acute or persistent gastrointestinal complaints, e.g. abdominal pain, nausea and vomiting.
- This medicine is taken for longer than three days.
- You experience dehydration

When administering this product to incontinent adults, pads should be changed more frequently to prevent extended skin contact with faeces.

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

Do not exceed the stated dose.

Laxatives do not help in long-term weight loss.

Pregnancy and breast-feeding

Do not take this medicine if pregnant or breastfeeding.

Important information about some of the ingredients of Senokot 7.5mg/5ml Syrup

This medicinal product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).

This medicine contains maltitol liquid (E965).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Caution is required if you are diabetic as each 5ml contains 3.2 kilocalories.

This medicine contains 6.9 mg of alcohol (ethanol) in each 5ml dose. The amount in each dose of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

Taking other medicines

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.

3. How to take Senokot 7.5mg/5ml Syrup

For oral use.

Adults, including the elderly and children 12 years old and over: the usual dose is one to two 5 ml spoonfuls at bedtime.

Do not exceed the stated dose.

Senokot 7.5mg/5ml Syrup usually works in 8-12 hours.

New users should start with the lowest dose and if needed increase by half the initial dose each day. When you feel the medicine is working, gradually reduce the dose and stop.

Duration of use: Normally it is sufficient to take this medicinal product 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.

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 diarrhoea¹. 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/5ml Syrup should be discontinued and only be restarted under medical supervision.

If you take more Senokot 7.5mg/5ml Syrup 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 hypo-kalaemia). 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 Senokot 7.5mg/5ml Syrup

If a dose is missed do not take or give a double dose, just carry on with the recommended dose. If you have any further questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

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

If any of the following or any other side effects occur, stop taking this medicine and consult a doctor or pharmacist:

- 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.
- chronic use may lead to albuminuria and haematuria which is albumin (protein) or red blood cells (blood) 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:**
Reporting 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 HPRA Pharmacovigilance, Website: www.hpra.ie

5. How to store Senokot 7.5mg/5ml Syrup

- **Keep all medicines out of sight and reach of children.**
- **Do not** store above 25°C. **Do not** freeze.
- **Do not** use after the expiry date shown on the pack.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Each 5ml of Senokot 7.5mg/5ml Syrup contains calcium sennosides equivalent to 7.5mg total sennosides (calculated as Sennoside B).

The other ingredients are potassium sorbate (E202), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), maltitol liquid (E965), xanthan gum, anti-foam (Medical C) emulsion, prune flavour (ethanol), citric acid anhydrous and purified water.

What Senokot 7.5mg/5ml Syrup looks like and the contents of the pack

Senokot 7.5mg/5ml Syrup is an amber coloured liquid available in 150ml bottle.

Marketing Authorisation Holder and Manufacturers

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

Manufacturers: Reckitt Benckiser Healthcare (UK) Limited, Dansom Lane, Hull, HU8 7DS, UK.

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