Senokot Tablet

Name and Strength of Active

Sennoside B - 7.5mg

Product Description

Circular, biconvex. greenish-brown tablet.

Pharmacodynamics

The sugar moiety of the sennosides is removed by bacteria in the large intestine releasing the active anthrone fraction. This stimulates peristalsis via the submucosal and myenteric nerve plexuses.

Defaecation takes place after a delay of 8 - 12 hours due to the time taken for transport to the colon and metabolisation into the active compound.

Pharmacokinetics

The action of the sennosides is colon specific and does not depend upon systemic absorption.

Indication

For relief of constipation and bowel evacuation prior to radiological examination.

Recommended Dose

Adults, the elderly and children over 18 years: Swallow one to two tablets at night

Children 18 years and under: Contraindicated in children under 18 years.

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

Route of Administration

Oral

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Not to be used at the same time as other laxative agents.

Cases of intestinal obstructions and stenosis, atony, appendicitis, inflammatory bowel diseases (e.g Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion

Do not use during pregnancy and lactation.

Warnings and Precautions

-If there is no bowel movement after three days, a doctor should be consulted.

-If laxatives are needed every day, or abdominal pain persists, a doctor should be consulted.

-If laxatives are needed every day the cause of the constipation should be investigated. Long-term use of laxatives should be avoided.

-The product contains lactose monohydrate. One tablet contains 15.82mg lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

-Do not exceed the stated dose.

-Patients taking cardiac glycosides, antiarrhythmic medicinal products, medicinal products inducing QT-prolongation, diuretics, adrenocorticosteroids or liquorice root, have to consult a doctor before taking this product concomitantly.

-Like all laxatives, this product should not be taken by patients suffering from faecal impaction and undiagnosed, acute or persistent gastro-intestinal complaints, e.g. abdominal pain, nausea and vomiting, unless advised by a doctor, because these symptoms can be signs of potential or existing intestinal blockage (ileus).

-If stimulant laxatives are taken for longer than a brief period of treatment, this may lead to impaired function of the intestine and dependence on laxatives. This product should only be used if a therapeutic effect cannot be achieved by a change of diet or the administration of bulk forming agents.

-Prolonged use may precipitate the onset of an atonic, non-functioning colon.

-Prolonged and excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

-Intestinal loss of fluids may promote dehydration. Symptoms may include thirst and oliguria.

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

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

-Should not be used in children or adolescents under the age of 18 year

-Laxatives do not help in long-term weight loss.

Interactions with Other Medicaments

Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products, with medicinal products, which induce reversion to sinus rhythm (e.g. quinidine) and with medicinal products inducing QT-prolongation. Concomitant use with

other medicinal products inducing hypokalaemia (e.g. diuretics, adrenocorticosteroids and liquorice root) may enhance electrolyte imbalance.

Pregnancy and Lactation

Pregnancy:

The use during pregnancy is contraindicated because of experimental data concerning a genotoxic risk of several anthranoids, e.g emodin and aloe-emodin.

Lactation:

Use during breastfeeding is contraindicated because small amounts of active metabolites (rhein) are excreted in breast milk.

Fertility:

There are no data on the effects of the product on fertility.

Side Effects

Adverse events which have been associated with senna at OTC doses in short-term use are given below, tabulated by system organ class and frequency.

In the treatment of chronic condition, under long-term treatment, additional adverse effects may occur.

Adverse events table		
System Organ Class	**Frequency**	**Adverse Events**
Immune System Disorders	Not known	Hypersensitivity, urticaria, asthma, hypogammaglobulinaemia
Metabolism and Nutrition Disorders	Not known	Hypokalaemia[1], cachexia
Gastrointestinal Disorders	Not known	Abdominal pain[2], abdominal spasm[2], diarrhoea[2], gastrointestinal tract mucosal pigmentation[3]
Skin and Subcutaneous Tissue Disorders	Not known	Pruritus, local or generalised exanthema
Musculoskeletal and Connective Tissue Disorders	Not known	Finger clubbing, tetany and hypertrophic osteoarthropathy
Renal and Urinary Disorders	Not known	Chromaturia4 , albuminuria, haematuria, electrolyte imbalance

Description of Selected Adverse Reactions

[1] Prolonged use of laxatives resulting in diarrhoea and subsequently hypokalaemia.

[2] in particular in patients with irritable colon. Symptoms may also occur generally as a consequence of individual overdosage. In such cases dose reduction is necessary.

[3] Chronic use may cause pigmentation of the intestinal mucosa (pseudomelanosis coli), which usually recedes when the patient stops taking the preparation.

[4] Yellow or red-brown (pH dependent) discolouration of urine by metabolites, which is not clinically significant, may occur during the treatment.

Chronic use may lead to disorders in water equilibrium and electrolyte metabolism and may result in albuminuria and haematuria.'

The frequency is not known (cannot be estimated from the available data).

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk of the medicinal product

Symptoms and Treatment of Overdose

Symptoms:

Where diarrhoea is severe, conservative measures are usually sufficient; generous amounts of fluid, especially fruit drinks, should be given.

The major symptoms of overdose/abuse are griping pain and severe diarrhoea with consequent losses of fluid and electrolytes, which should be replaced.

Diarrhoea may especially cause potassium depletion, which may lead to cardiac disorders and muscular asthenia, particularly where cardiac glycosides, diuretics, adrenocorticosteroids or liquorice root are being taken at the same time.

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

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Treatment:

Treatment should be supportive with generous amounts of fluid. Electrolytes, especially potassium, should be monitored. This is especially important in the elderly. Chronic ingested overdoses of anthranoid containing medicinal products may lead to toxic hepatitis.

Storage Conditions

Store dry below 25℃ in the original package to protect from moisture.

Shelf Life

3 years

Packaging available:

60 Tablet

Manufacturer:

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