PRESCRIBING INFORMATION

INCLUDING PATIENT MEDICATION INFORMATION

Senokot®•S

Senna (Standardized Sennosides) / Docusate Sodium Tablets

8.6 mg / 50 mg

Purdue Pharma Standard

STIMULANT LAXATIVE / STOOL SOFTENER

Purdue Pharma
3381 Steeles Ave E
Markham,
ON M2H 3S7

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TABLE OF CONTENTS

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

Senokot®•S (senna and docusate sodium tablets) is indicated for:

- gentle overnight relief of occasional constipation
- softens the stool

1.1 Pediatrics

Pediatrics (6 years and older): The safety and efficacy of Senokot•S· in pediatric patients 6 years and older has been established; therefore, an indication for pediatric use in children 6 years and older has been authorized (see Section 3.2).

1.2 Geriatrics

Geriatrics (> 65 years of age): Evidence from literature and experience suggests that use in the geriatric population is not associated with differences in safety or effectiveness.

2 CONTRAINDICATIONS

Senna and docusate sodium tablets are contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see DOSAGE FORMS, STRENGTHS, COMPOSITION and PACKAGING.

- acute surgical abdomen
- abnormal constrictions of the gastrointestinal tract
- potential or existing intestinal obstruction and stenosis
- ileus
- atonic bowel
- appendicitis
- inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- abdominal pain of unknown origin
- undiagnosed rectal bleeding
- severe dehydration

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Not recommended when:

- pregnant
- breastfeeding

4.2 Recommended Dose and Dosage Adjustment

Adults and children 12 years and older

1 to 2 tablets at bedtime, as required. Maximum 4 tablets twice a day. Do not take more than 8 tablets in 24 hours.

Children (6 to 11 years)

½ to 1 tablet at bedtime. Maximum 1 tablet, twice a day. Do not take more than 2 tablets in 24 hours.

4.4 Administration

It is recommended to take Senokot•S (senna and docusate sodium tablets) at night to have a bowel movement the following morning. Evacuation generally occurs within 6 to 12 hours following ingestion.

The correct dose of the sennosides-containing laxatives is the smallest required to produce comfortable soft-formed stool and varies between individuals.

Drink increased fluids (one full glass or more) with each dose.

5 OVERDOSAGE

The major symptoms of overdose/abuse of stimulant laxatives, including those containing senna, are griping pain and severe diarrhea, leading to excessive water loss (dehydration) and possible electrolyte imbalance (i.e., hypokalemia). Symptoms of dehydration may include thirst and oliguria.

Treatment should be supportive with generous amounts of fluid. Electrolytes, especially potassium, should be monitored. This is especially important in the elderly and the young.

Administration of antispasmodics may be of value.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
oral	orange, film-coated tablet, stamped S/S on one side 8.6 mg / 50 mg	Corn starch, D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, guar gum, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, sodium benzoate, talc and titanium dioxide

Also contains corn starch. Sodium: <1 mmol (2.6 mg). Tartrazine free. Supplied in

blisters of 10 tablets and bottles of 20, 60, 120 and 1,000 tablets.

7 WARNINGS AND PRECAUTIONS

General

As with all laxatives, patients should be advised to not take Senokot•S (senna and docusate sodium tablets) for more than one week. If symptoms continue to occur or worsen and laxatives are needed every day or if there has been a sudden change in bowel movements that persists over a period of 2 weeks, the cause of the constipation should be investigated.

For patients on a sodium-restricted diet, there is a very small amount of sodium in Senokot•S (see DOSAGE FORMS, STRENGTHS, COMPOSITION and PACKAGING).

Dependence/Tolerance

Long-term use of stimulant laxatives should be avoided as it may lead to impaired function of the intestine, dependence on laxatives, dehydration and electrolyte imbalance (including hypokalemia).

Prolonged excessive use or misuse of laxatives may also result in the development of atonic colon.

Reversible pigmentation of the colon, i.e., melanosis coli, may also result from prolonged use of senna containing preparations.

Driving and Operating Machinery

No studies on the effects of the ability to drive and use machines have been performed. However, patients should be advised that due to a vasovagal response (e.g., to abdominal spasm) they may experience dizziness and/or syncope. If patients experience abdominal spasm they should avoid potentially hazardous tasks such as driving or operating machinery.

Gastrointestinal

Reduce dose or discontinue use in the presence of abdominal pain, griping (cramps or spasms) and/or diarrhea.

Do not use in the presence of fecal impaction and undiagnosed, acute or persistent gastrointestinal complaints (e.g., abdominal pain, nausea, fever or vomiting) as these symptoms can be signs of a potential or existing intestinal blockage or ileus, appendicitis or inflamed bowel.

If rectal bleeding or failure to have a bowel movement (after use of a laxative) occurs, therapy should be discontinued as it may indicate a more serious condition.

Genitourinary

Urine discolouration (chromaturia), if present, may interfere with the interpretation of laboratory tests (see Monitoring and Laboratory Tests).

Monitoring and Laboratory Tests

Due to the presence of chrysophanic acid in natural senna, Senokot·S (senna and docusate sodium tablets) may cause discolouration of urine, or feces depending on the acidity (yellow- brown discolouration) or alkalinity (red-violet discolouration) of the substance. There is no pathologic significance to this discolouration.

Renal

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

7.1 Special Populations

7.1.1 Pregnant Women

There are no reports of adverse or damaging effects during pregnancy or on the fetus associated with senna preparations when used in accordance to the recommended dosage schedule. However, as a consequence of experimental data concerning a genotoxic risk of several anthranoids (e.g., emodin and aloe-emodin), use is not recommended during pregnancy.

7.1.2 Breastfeeding

Small amounts of active metabolites (rhein) are excreted in breast milk. A laxative effect in breast fed babies has not been reported. However, use during breastfeeding is not recommended as there are insufficient data on the excretion of metabolites in breast milk.

7.1.3 Pediatrics

Pediatrics (6 to 11 years): The safety and efficacy of Senokot•S in pediatric patients under the age of 6 years has not been established; therefore, an indication for pediatric use has only been authorized in children 6 years and older (see Section 3.2).

7.1.4 Geriatrics

Intestinal loss of fluids can promote dehydration. Symptoms may include thirst and oliguria. In patients suffering from fluid loss where dehydration may be harmful (e.g., renal insufficiency, elderly patients). Senokot-S should be discontinued and only be restarted under medical supervision.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The most common reported adverse event in clinical trials was abdominal pain/discomfort. The following adverse events are those obtained through extensive post-marketing use and/or literature, not clinical trials (see Section 7.3).

8.4 Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data

Due to the presence of chrysophanic acid in natural senna, sennoside-containing laxatives may cause discoloration of feces and / or pH dependent discoloration of the urine (yellow-brown discoloration in acidic urine and red-violet discoloration in alkaline urine). There is no pathologic significance to this discoloration. Urine discoloration (chromaturia), if present, may interfere with the interpretation of laboratory tests.

8.5 Post-Market Adverse Reactions

The undesirable effects listed below are classified by body system according to their incidence. Common undesirable effects have an incidence of > 1% and uncommon undesirable effects have an incidence of < 1%.

Gastrointestinal Disorders

Common: abdominal pain

Uncommon: faeces discoloured, nausea, perianal irritation, rectal hemorrhage, vomiting Not known: diarrhea

Immune System Disorders

Uncommon: urticaria

Very rare: anaphylactic reaction, anaphylactoid reaction

Not known: hypersensitivity

Renal and Urinary Disorders

Uncommon: chromaturia

Skin and Subcutaneous Tissue Disorders

Uncommon: rash erythematous, rash maculo-papular

Not known: pruritus

9 DRUG INTERACTIONS

Overview

Laxatives should not be taken within two hours of another medicine because the desired effect of the other medicine may be reduced.

9.4 Drug-Drug Interactions

Interactions with other drugs have not been clinically established.

Concomitant therapy with other drugs known to induce hypokalemia (e.g., thiazide diuretics, adreno corticosteroids) may enhance the electrolyte imbalance. Hypokalemia potentiates the action of cardiac glycosides and interacts with antiarrhythmic medications.

Use with caution in patients taking mineral oil as the docusate sodium component of Senokot•S (senna and docusate sodium tablets) may increase absorption of oil from the gastrointestinal tract, leading to toxicity.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Concomitant therapy with other herbal substances known to induce hypokalemia (e.g., liquorice root) may enhance the electrolyte imbalance. Hypokalemia potentiates the action of cardiac glycosides and interacts with antiarrhythmic medications.

9.7 Drug-Laboratory Test Interactions

Due to the presence of chrysophanic acid in natural senna, Senokot•S (senna and docusate sodium tablets) may cause discolouration of urine, or feces depending on the acidity (yellow- brown discolouration) or alkalinity (red-violet discolouration) of the substance. There is no pathologic significance to this discolouration.

10 ACTION AND CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

The laxative agent in Senokot•S (senna and docusate sodium tablets) is a natural vegetable derivative (senna) standardized for predictable results. The principal constituents of Senokot•S are senna glycosides. These include sennosides A & B, and the glycoside derivatives of rhein and chrysophanic acid. These glycosides, when converted into aglycones in the colon, function as laxative agents.

Only minimal amounts of the metabolites of senna (aglycones) are absorbed systemically. The actual extent to which such metabolites are distributed to body tissues and fluids is unknown; they may be excreted in the bile and have been detected in small amounts in breast milk.

Docusate sodium is a surface-active agent that acts by allowing water and fats to enter the stools, which helps hydrate and soften the stools making it useful in the relief of occasional constipation.

Senokot•S has potential benefits for palliative care and postpartum patients, for patients with heart disease where straining when passing stool must be avoided, and in constipation in the presence of hemorrhoids, anal fissures or other conditions where hard, dry stools may cause discomfort.

10.2 Pharmacodynamics

The laxative principles of the senna plant have been identified as sennosides (senna glycosides). Enzymatic action by colonic bacteria converts the glycosides into aglycones, which induce colonic peristalsis through stimulation of the intrinsic peristaltic mechanism in the colonic wall. This action is virtually colon-specific, since these compounds have little or no action in the stomach and small intestine. The stimulant effect on the Myenteric (Auerbach's) plexus in the colonic wall is reportedly free of mucosal injury. Senna also has effects on electrolyte and water transport.

Preclinical Safety Data

Results from published acute, sub-chronic and chronic toxicology studies as well as genotoxicity and reproductive studies with senna or docusate sodium indicate that these ingredients are safe when used as recommended. In a GLP compliant carcinogenicity study, lifetime exposure to senna did not result in any evidence of carcinogenicity in rats dosed at levels as high as 300 mg/kg/day. Finally, in a published (non-GLP compliant) two-year carcinogenicity study, rats fed diets containing as high as 1% docusate sodium (about 200 mg/day) showed no treatment-related lesions.

11 STORAGE, STABILITY AND DISPOSAL

Store at 15°C to 25ºC.

Keep out of the sight and reach of children.

12 SPECIAL HANDLING INSTRUCTIONS

None.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Senokot®•S

Senna (standardized sennosides) and docusate sodium tablets

Read this carefully before you start taking Senokot®•S. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Senokot•S.

What is Senokot•S used for?

- gentle relief of occasional constipation (irregularity)
- softens the stool

How does Senokot•S work?

Senokot•S contains two active ingredients, senna (standardized sennosides) and docusate sodium. Senna increases the wave-like muscle activity in your lower gut to help move stool through your bowel. The docusate sodium softens the stool for easier passing.

What are the ingredients in Senokot•S

Medicinal ingredients: Standardized sennosides from senna and docusate sodium**.**

Non-medicinal ingredients: Corn starch, D&C Yellow No.10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, guar gum, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, sodium benzoate, talc and titanium dioxide.

Senokot•S comes in the following dosage forms:

Tablets containing 8.6 mg standardized sennosides and docusate sodium 50 mg.

Do not use Senokot•S if you have:

- an allergy to sennosides (senna), docusate sodium or any other ingredient in the tablets
- severe abdominal pain that begins suddenly
- abnormal cramping or narrowing in your throat, stomach or intestines
- lack of muscle tone or strength in the colon
- appendicitis
- inflamed bowels or a bowel disease such as Crohn's or bowel ulcers
- abdominal pain of unknown origin
- undiagnosed rectal bleeding
- severe dehydration
- fecal impaction (a large lump of dry, hard stool that develops in the rectum)

- intestinal blockage
- undiagnosed, acute or persistent gastrointestinal complaints (e.g., abdominal pain, nausea, fever or vomiting)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Senokot•S. Talk about any health conditions or problems you may have, including if you:

- are pregnant or breastfeeding
- have a kidney problem
- take heart medications, water pills, steroids, licorice root or other medications which may worsen electrolyte balance

Other warnings you should know about:

Reduce dose or discontinue use if you experience abdominal pain, cramps or spasms and/or diarrhea.

Do not take Senokot•S or any other laxative for more than one week. If laxatives are needed every day, consult a healthcare professional.

Long-term use of stimulant laxatives should be avoided. Prolonged excessive use or misuse may cause loss of bowel function.

If rectal bleeding or failure to have a bowel movement occurs after use, do not take another dose and consult a doctor as there may be a more serious condition.

If you have a sudden change in your bowel movements that lasts more than 2 weeks, consult a doctor before taking this product or any laxative.

There is a very small amount of sodium (less than 2.6 mg) in Senokot•S. Consult a

healthcare practitioner if symptoms continue to occur or worsen.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Senokot•S should not be taken within 2 hours of another medicine as it may reduce the effectiveness of the other medicine.

The following may interact with Senokot•S:

- Mineral oil - docusate sodium may increase the absorption of mineral oil from the gastrointestinal tract leading to toxicity.
- Cardiac medications such as cardiac glycosides (drug that increase the force of contraction of the heart) or antiarrhythmic medications (drugs that restore the normal rhythm of the heart).
- Thiazide diuretics (drugs used to treat high blood pressure), corticosteroids, liquorice root or other medications or health products which may worsen electrolyte imbalance.

How to take Senokot•S:

Take preferably at bedtime. A bowel movement generally occurs within 6 to 12 hours. The correct dose is the smallest amount required to produce a comfortable soft-formed stool. This varies between people. Drink increased fluids (one full glass or more) with each dose.

Usual dose:

Adults and children 12 years and older:

1 to 2 tablets at bedtime, as required. Maximum 4 tablets twice a day (8 tablets in 24 hours).

Children (6 to 11 years):

½ to 1 tablet at bedtime. Maximum 1 tablet twice a day (2 tablets in 24 hours).

Overdose:

The major symptoms of overdose are abdominal pain and severe diarrhea leading to excessive water loss (dehydration) and possible electrolyte imbalance (i.e. low potassium).

If you think you have taken too much **Senokot•S**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Senokot•S?

The most common side effect you may experience is abdominal pain.

The uncommon and very rare side effects include: anaphylactic and anaphylactoid reactions (severe allergic reactions), chromaturia (urine discolouration), feces discolouration, nausea, rash erythematous (redness and skin inflammation surrounding a patch of skin where a rash is located), rash maculo-papular (red bumpy skin), perianal irritation (skin irritation surrounding the anal area), rectal hemorrhage (severe bleeding in the rectal area), urticaria (raised red, itchy areas on the skin also known as hives) and vomiting.

Other side effects may include: diarrhea, hypersensitivity and pruritus (itching).

These are not all the possible side effects that you may feel when taking **Senokot•S**. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON abdominal pain (cramps or spasms)	√		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON bleeding in the rectal area			√
VERY RARE allergic reaction			√
diarrhea	**√**		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15°C to 25ºC). Keep

out of reach and sight of children.

If you want more information about Senokot•S:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); the manufacturer's website (purdue.ca), or by calling 1-800-387-4501.

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