

PRESCRIBING INFORMATION

Senokot[®]•S

**Senna (Standardized Sennosides) / Docusate Sodium Tablets
8.6 mg / 50 mg**

Purdue Pharma Standard

PERISTALTIC STIMULANT - STOOL SOFTENER

Purdue Pharma
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Pickering, ON
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PRESCRIBING INFORMATION

NAME OF DRUG

Senokot®•S

Senna (Standardized Sennosides) / Docusate Sodium Tablets

PHARMACOLOGICAL CLASSIFICATION

Peristaltic Stimulant - Stool Softener

ACTIONS

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.

Pharmacodynamic Properties

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, subchronic 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.

INDICATIONS

Senokot®•S (senna and docusate sodium tablets) is indicated for gentle overnight relief of occasional constipation and softens the stools.

CONTRAINDICATIONS

- known hypersensitivity to one or both of the active substances (senna or docusate sodium) or to any ingredient in the formulation (see **PHARMACEUTICAL INFORMATION**);
- 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.

WARNINGS AND PRECAUTIONS

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.

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.

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.

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.

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

For patients on a sodium-restricted diet, there is a very small amount of sodium in **Senokot•S** (senna and docusate sodium tablets) (see **AVAILABILITY**).

Fertility, Pregnancy and Lactation

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 aloë-emodin) use is not recommended during pregnancy.

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.

Monitoring and Laboratory Tests

Urine discolouration (chromaturia), if present, may interfere with the interpretation of laboratory tests.

DRUG INTERACTIONS

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

Concomitant therapy with other drugs or herbal substances known to induce hypokalemia (e.g., thiazide diuretics, adrenocorticosteroids and liquorice root) 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.

ADVERSE REACTIONS

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. Urine discolouration (chromaturia), if present, may interfere with the interpretation of laboratory tests (see **Monitoring and Laboratory Tests**). Reversible pigmentation of the colon, i.e., melanosis coli, may also result from prolonged use of senna containing preparations.

The adverse reactions listed below are classified according to their incidence (common or uncommon). Common adverse reactions have an incidence of $\geq 1\%$ and include the following: abdominal pain. Uncommon adverse reactions have an incidence of $< 1\%$ and include the

following: anaphylactic reaction, anaphylactoid reaction, breast milk discolouration, chromaturia, feces discoloured, nausea, rash erythematous, rash maculo-papular, perianal irritation, rectal hemorrhage, urticaria and vomiting. Adverse reactions of unknown frequency include the following: diarrhea, hypersensitivity and pruritus.

SYMPTOMS AND TREATMENT OF 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.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DOSAGE AND ADMINISTRATION

Administer preferably at bedtime. 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.

Adults and children 12 years and older

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

Use during pregnancy or breastfeeding is not recommended (see **WARNINGS AND PRECAUTIONS**).

Children (6 to 11 years)

½ to 1 tablet at bedtime. Maximum 1 tablet, twice a day (2 tablets/day).

PHARMACEUTICAL INFORMATION

Active Ingredients

Senna is deseeded and dried pods of *Cassia acutifolia* Delile known in commerce as Alexandria senna.

The chemical name of docusate sodium is butanedioic acid, sulfo-, 1,4-bis (2-ethylhexyl) ester, sodium salt.

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.

AVAILABILITY

Each orange, film-coated tablet, stamped S/S on one side, contains: standardized sennosides 8.6 mg and docusate sodium 50 mg. Also contains corn starch. Sodium: <1 mmol (2.6 mg). Tartrazine free. Supplied in packages of 10, bottles of 20, 60 and 1,000 tablets.

STORAGE AND STABILITY

Store at 15°C to 25°C.

Keep out of the sight and reach of children.

CONSUMER INFORMATION

Senokot®•S
Senna (Standardized Sennosides) /
Docusate Sodium

This leaflet is part of the “Prescribing Information” published for Senokot®•S and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Senokot®•S. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

Senokot®•S contains senna (a laxative) and docusate sodium (a stool softener) which are used to relieve occasional constipation and softens the stools.

What it does:

Senokot®•S contains two medicinal ingredients, senna (standardized sennosides) and docusate sodium. The senna component stimulates wave-like muscle contractions in the intestines (gut) called peristalsis, therefore resulting in a bowel movement and the docusate sodium softens the stool to allow for easier passage of it.

When it should not be used:

Senokot®•S should not be used if you:

- are allergic to sennosides, docusate sodium or any other ingredient in the tablets (see **What the non-medicinal ingredients are:**);
- have “acute surgical abdomen” (abdominal pain that begins suddenly and is severe in nature);
- have abnormal cramping or narrowing in your throat, stomach or intestines;
- have a potential or existing intestinal blockage or non-functioning bowel (lack of normal muscle tone or strength in the colon);
- have appendicitis;
- have inflammatory bowel disease such as Crohn’s disease or ulcerative colitis;
- have abdominal pain of unknown origin;
- have undiagnosed rectal bleeding.
- have severe dehydration

What the medicinal ingredients are:

Standardized sennosides from senna and docusate sodium

What the non-medicinal ingredients are:

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

Each **Senokot®•S** tablet contains less than 2.6 mg of sodium.

What dosage forms it comes in:

Senokot®•S Tablets: 8.6 mg standardized sennosides from a natural source and 50 mg docusate sodium

WARNINGS AND PRECAUTIONS

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

Do not use in:

- the presence of fecal impaction (a large lump of dry, hard stool that develops in the rectum);
- undiagnosed, acute or persistent gastrointestinal complaints (e.g., abdominal pain, nausea, fever or vomiting)
- appendicitis; inflamed bowel;
- intestinal blockage.

Consult a healthcare practitioner if symptoms continue to occur or worsen.

As with all laxatives, do not take for more than one week. If laxatives are needed every day, consult a healthcare practitioner. Long-term use of stimulant laxatives should be avoided. Prolonged excessive use or misuse may precipitate the onset of atonic (non-functioning) colon.

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 - consult a physician.

If there has been a sudden change in bowel movements that persists over a period of 2 weeks, consult a physician before using a laxative.

Consult a healthcare practitioner prior to use if you have a kidney disorder, are pregnant or breastfeeding.

INTERACTIONS WITH THIS MEDICATION

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

Drugs that may interact with **Senokot®•S** include:

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

PROPER USE OF THIS MEDICATION**Usual dose:**

Administer preferably at bedtime. A bowel movement 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.

Adults and children 12 years and older:

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

Children (6 to 11 years):

½ to 1 tablet at bedtime. Maximum 1 tablet twice a day (2 tablets/day).

Overdose:

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

In case of overdose, call a Regional Poison Control Centre and/or your physician and/or your local emergency number immediately, or go to your local hospital emergency, even if you do not notice any signs or symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

The uncommon side effects include: anaphylactic reaction and anaphylactoid reactions (severe allergic reactions), breast milk discoloration, chromaturia (urine discoloration), feces discoloration, 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).

For any unexpected effects while taking Senokot•S, contact your doctor or pharmacist.

HOW TO STORE IT

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

Keep out of the sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This leaflet summarized important information about Senokot•S. If you would like more information, talk with your doctor and/or pharmacist.

This document plus the full Prescribing Information, prepared for health professionals can be found at: <http://www.purdue.ca> or by contacting the manufacturer, Purdue Pharma, at: 1-800-387-4501.

This leaflet was prepared by Purdue Pharma.

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