PRESCRIBING INFORMATION

Senokot®•S

Senna (Standardized Sennosides) / Docusate Sodium

Tablets, 8.6 / 50 mg

Purdue Pharma Standard

PERISTALTIC STIMULANT - STOOL SOFTENER

Purdue Pharma
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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** 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 is indicated for the gentle relief of occasional constipation and softens the stools.

CONTRAINDICATIONS

Do not use if you are hypersensitive to one or both of the active substances (senna or docusate sodium) or to any ingredient in the formulation, or have an "acute surgical abdomen", abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease such as Crohn's disease or ulcerative colitis, abdominal pain of unknown origin, undiagnosed rectal bleeding and severe dehydration with depleted water or electrolytes.

WARNINGS AND PRECAUTIONS

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

Do not use in the presence of fecal impaction, abdominal pain, nausea, fever or vomiting (this refers to signs of appendicitis or inflamed bowel) unless directed by a physician.

Consult a health care practitioner if symptoms persist or worsen.

As with all laxatives, do not take for more than one week without consulting your physician.

Overuse or extended use may cause dependence for bowel function.

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

Rectal bleeding or continuous failure to have a bowel movement after use of a laxative may indicate a more serious condition. Discontinue use and 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.

If pregnant or breast-feeding, consult a physician before using this product.

Consult a health care practitioner prior to use if you have a kidney disorder.

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

Drug Interactions
Consult a health care practitioner prior to use if you are taking thiazide diuretics, corticosteroids, liquorice root or other medications or health products which may aggravate electrolyte imbalance.

Consult a health care practitioner prior to use if you are taking cardiac medications such as cardiac glycosides or antiarrhythmic medications.

Do not administer concomitantly with mineral oil since the docusate sodium component of **Senokot®•S** (senna and docusate sodium) tablets may increase absorption of oil.

ADVERSE REACTIONS

In clinical trials, adverse effects were seen in approximately 4% of the cases; in about one-third of these, the effects were ascribed to dose being too high. Most frequently these consisted of cramps and/or griping, usually described as "mild" or "slight", or "occasional", which are extensions of the activities associated with bowel evacuation. Only 0.21% of cases were reported as severe cramping; in some cases this resulted in cessation of treatment.

Due to the presence of chrysophanic acid in natural senna, **Senokot®** laxatives may cause discolouration of breast milk, 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 undesirable effects listed below are classified according to their incidence (common or uncommon). Common undesirable effects have an incidence of ≥ 1% and include the following: abdominal pain. Uncommon undesirable effects 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.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Prolonged use or overdosage with any stimulant laxative including those containing senna may cause diarrhea, leading to excessive water loss (dehydration) and possible electrolyte imbalance.

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

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:
1 to 2 tablets at bedtime, as required. Maximum, 4 tablets twice a day.

If pregnant or breast-feeding consult a physician.

Children (6 to 12 years):
½ to 1 tablet at bedtime, not to exceed 1 tablet twice a 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.

Composition: corn starch, guar gum, magnesium stearate, microcrystalline cellulose, silicon dioxide and sodium benzoate. Film coating: D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, lecithin, polyethylene glycol, polyvinyl alcohol, 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 Conditions: Store at 15-25º C.

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:**);
- You have "acute surgical abdomen" (abdominal pain that begins suddenly and is severe in nature);
- You have abnormal constrictions of the gastrointestinal tract (esophagus, stomach, small and large intestines), potential or existing intestinal blockage, atonic bowel (lack of normal muscle tone or strength in the colon), appendicitis, inflammatory colon disease such as Crohn's disease or ulcerative colitis, abdominal pain of unknown origin, undiagnosed rectal bleeding and severe dehydration with depleted water or electrolytes (chemicals found in the bloodstream that regulate the electrical charge and water flow in the bloodstream).

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

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) or abdominal pain, nausea, fever or vomiting (this refers to signs of appendicitis or inflamed bowel).

Consult a health care practitioner if symptoms continue to occur or worsen.

As with all laxatives, do not take for more than one week without consulting your physician.

Overuse or long-term use can make your bowels dependent on this medication to function.

Rectal bleeding or continuous failure to have a bowel movement after use of a laxative may indicate a more serious condition. Discontinue use and 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.

If pregnant or breast-feeding, consult a physician before using this product.

Consult a health care practitioner prior to use if you have a kidney disorder.

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 aggravate 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:
1 to 2 tablets at bedtime, as required. Maximum, 4 tablets twice a day.

If pregnant or breast-feeding consult a physician.

Children (6 to 12 years):
½ to 1 tablet at bedtime, not to exceed 1 tablet twice a day.

Overdose:
Prolonged use or overdosage with any stimulant laxative including those containing senna may cause diarrhea, leading to excessive water loss (dehydration) and possible electrolyte imbalance.

Prolonged excessive use or misuse of these products may also result in the development of atonic colon (lack of normal muscle tone or strength in the colon).

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 discolouration, 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.

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

HOW TO STORE IT

Store tablets at room temperature (15 - 25˚C).

Keep out of 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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