

PRESCRIBING INFORMATION

**Senokot[®]•S
Tablets**

**Senna (Standardized Sennosides from Senna Concentrate CG)
Docusate Sodium**

Purdue Pharma Std.

PERISTALTIC STIMULANT - STOOL SOFTENER

Purdue Pharma
575 Granite Court
Pickering, ON
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DATE OF REVISION:
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PRESCRIBING INFORMATION

NAME OF DRUG

**Senokot®•S
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 useful in the medical management of certain types of constipation and fecal impaction.

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

Relief of functional constipation through combined stool softening and peristaltic stimulation. Specifically indicated for postpartum patients, for use by patients with heart disease where straining at stool must be avoided, and in constipation in the presence of hemorrhoids, anal fissures or other conditions where hard, dry stools may cause discomfort.

CONTRAINDICATIONS

The "acute abdomen".

WARNINGS AND PRECAUTIONS

If griping occurs, subsequent dosage should be reduced. Administer with caution to nursing mothers.

Do not use in the presence of abdominal pain, nausea, fever or vomiting.

Overuse or extended use may cause dependence for bowel function.

Do not take any type of laxative for more than one week, unless your physician has ordered a special schedule.

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

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.

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a 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. Laxative products should not be used for a period longer than 1 week unless directed by a doctor.

If pregnant or nursing, seek the advice of a health care professional before using this product.

Drug Interactions: There are no known drug interactions with sennosides.

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. Nausea and vomiting may also occur. Hypersensitivity skin reactions are an uncommon occurrence; very rarely anaphylactoid reactions have been reported.

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, if present may interfere with the interpretation of laboratory test. Prolonged use of these products 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; this effect is considered benign.

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 and possible electrolyte imbalance.

In case of accidental overdosage, seek professional assistance.

DOSAGE AND ADMINISTRATION

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.

Tablets:*Adults:*

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

Pregnancy and children (6 to 12 years):

½ to 1 tablet at bedtime, not to exceed 2 tablets 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. 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

Tablets: Each orange, film-coated tablet, stamped S/S on one side, contains: standardized sennosides 8.6 mg and docusate sodium 50 mg. Also contains cornstarch. 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 room temperature (15-25° C).