

Product Licence Licence de mise en marché

Product Number/Numéro de produit: 00026158

Brand Name/Marque nominative: Senokot Tablets

Issued to/Émise à:

Name of licensee/Nom du titulaire:

Purdue Pharma
575 Granite Court
Pickering, Ontario, L1W 3W8
Canada

Authorized for the following/Autorisé pour ce qui suit:

Dosage form/Forme posologique: Tablet

Recommended route of administration/Voie d'administration recommandée:

Oral

Recommended dose/Dose recommandée:

- | | |
|---------------------------|--|
| Adults : | Take 2 - 4 tablets 1 - 2 times per day. Take at bedtime, as required. Maximum, 4 tablets twice a day. Administer preferably at bedtime. Evacuation generally occurs within 6-12 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. |
| Children (6 to 12 years): | Take 1 - 2 tablets 1 - 2 times per day. Take at bedtime, not to exceed 2 tablets twice a day. Administer preferably at bedtime. Evacuation generally occurs within 6-12 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. |
| Adults (Pregnant) : | Take 1 - 2 tablets 1 - 2 times per day. Take at bedtime, not to exceed 2 tablets twice a day. Administer preferably at bedtime. Evacuation generally occurs within 6-12 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. |

Recommended duration of use/Durée d'utilisation recommandée:

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

Recommended use or purpose/Usage ou les fins recommandés:

For relief of functional constipation (occasional). The natural source senna in all Senokot products provides comfortable, overnight relief from occasional constipation.

Risk Information/Renseignements sur les risques:

Cautions and Warnings

If griping occurs, reduce dosage. Administer with caution to nursing mothers. Do not use in the presence of abdominal pain, nausea, fever or vomiting unless directed by a physician. Overuse or extended use may cause dependence for bowel function. Consult a health care practitioner if symptoms persist or worsen. 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. 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 physician. If pregnant or nursing, seek the advice of a health care practitioner before using this product. Consult a health care practitioner prior to use if you are taking heart medications, diuretics, adrenocorticosteroids, licorice root or other health products that may aggravate electrolyte imbalance. 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. Keep all medicines out of the reach of children. Drug Interactions: There are no known drug interactions with sennosides. 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.

Contra-Indications

The "acute abdomen." Do not use if you have intestinal obstructions and/or stenosis, atony, appendicitis, inflammatory colon disease (e.g. Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, and/or a severe dehydration state with water and electrolyte depletion.

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Known 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 tests. Prolonged use or misuse 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.

Medicinal Ingredients/Ingrédients médicinaux:

Proper Name Nom propre	Common Name Nom usuel	Quantity per Dosage Unit Quantité par unité posologique	Extract Extrait	Potency Activité	Source Material Matière d'origine
Standardized Sennosides	Standardized Sennosides	8.6 mg	N/A	8.6 mg Standardized Sennosides	Dried pods of Cassia acutifolia Delile

This licence is issued by the Minister of Health under the authority of section 7 of the Natural Health Products Regulations. Sale of the described natural health product, including any changes thereto pursuant to section 11 of the Regulations, is subject to the Food and Drugs Act and to the Natural Health Products Regulations.

Cette licence est émise par la ministre de la Santé en vertu de l'article 7 du Règlement sur les produits de santé naturels.

La vente du produit de santé naturel décrit dans la présente, y compris toute modification afférente au sens de l'article 11 du Règlement, est assujettie à la Loi sur les aliments et drogues et au Règlement sur les produits de santé naturels.

Issued/émis le: 2009-11-23

Revised/Amended/Modifié le: 2010-01-05



Director General/Directrice générale
NHPD/DPSN