Health Canada / Santé Canada

Product Licence
Licence de mise en marché

Product Number/*Numéro de produit*: 00367729
Brand Name/*Marque nominative*: Senokot Syrup
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*: Syrup
Recommended route of administration/Voie *d'administration recommandée:*

Oral

Recommended dose/*Dose recommandée:*

Adults :	10-15 mL (2-3 teaspoons) 1-2 times per day. Take at bedtime, as required. Maximum, 15 mL 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) :	5-10 mL (1-2 teaspoons) 1-2 times per day. Take at bedtime, not to exceed 10 mL twice a day. Adjust dosage as necessary. 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): 5-10 mL (1-2 teaspoons) 1 - 2 times per day. Take at bedtime, not to exceed 10 mL twice a day. Adjust dosage as necessary. 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.
Infants :	(Less than 2 years): Consult physician.
Children :	(2 to 5 years): Consult a healthcare professional.

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). Promotes bowel movement by direct action on the large intestine. The natural source senna in all Senokot products provides comfortable, overnight relief from occasional constipation.

Risk Information/*Renseignements sur les risques:*

Cautions and Warnings

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 unless directed by a physician. Consult a health care practitioner if symptoms persist or worsen. 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. 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 thiazide diuretics, corticosteroids, licorice root or other medications or health products which may aggravate electrolyte imbalance. Consult a health care practitioner prior to use if you have a kidney disorder or are taking cardiac medications such as cardiac glycosides or antiarrhythmic medications.
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 (dehydration) and possible electrolyte imbalance. Prolonged excessive use or misuse of these products may also result in the development of atonic colon. In case of overdose: Call a Regional Poison Control Centre

Canada

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and/or your physician and/or you 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.

Contra-Indications

The "acute abdomen." Do not use if you have 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.

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. 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. 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.

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	1.7 mg/ml	N/A	1.7 mg/ml 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: 2009-11-13	Revised/Amended/Modifié le: 2012-04-11

Director General/*Directeur général*
NHPD/*DPSN*