Product Licence
Licence de mise en marché

Product Number/*Numéro de produit*: 00026158
Brand Name/*Marque nominative*: Senokot
Other Brand Name(s)/Autre(s) marque(s) nominative(s):
Senokot For Women
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 to 4 tablets, once or twice a day. Maximum 8 tablets/day. 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.
Children :	(6 to 12 years): Take 1 to 2 tablets, once or twice a day, as required. Maximum 4 tablets/day. 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.

Recommended duration of use/*Durée d'utilisation recommandée:*

As with all laxatives, do not take for more than one week. If laxatives are needed every day, the cause of the constipation should be investigated.

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 and undiagnosed, acute or persistant 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. Consult a healthcare practitioner if symptoms persist or worsen. Laxatives should not be taken within two hours of another medicine because the desired effect of the other medicine may be reduced. If rectal bleeding or failure to have a bowel movement (after use occurs, discontinue therapy and consult a physician, as this may indicate a serious condition. If there has been a sudden change in your bowel movements that persists over a 2 week period, consult a physician before use. Consult a physician 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 physician prior to use if you have a kidney disorder or are taking cardiac medications such as cardiac glycosides or antiarrhythmic medications. 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). Concomitant therapy with other drugs or herbal substances known to induce hypokalemia (e.g. diuretics, adrenocorticosteroids and liquorice root) may enhance the electrolyte imbalance. Prolonged excessive use or misuse of these products may also result in the development of atonic colon. Fertility, Pregnancy and Lactation: Consult a physician before use. There are no reports of undesirable or damaging effects during pregnancy or on the fetus associated with senna preparations when used in accordance with the recommended dosage schedule. However, as a consequence of experimental data concerning a genotoxic risk of several anthranoids (e.g. emodin and aloe-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. Symptoms and Treatment of Overdosage: The major

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symptoms of overdose abuse of any stimulant laxative, including those containing senna, are gripping pain and severe diarrhea, leading to excessive water loss (dehydration) and possible electrolyte imbalance (hypokalemia). Treatment should be supportive with generous amounts of fluid. Electrolytes, especially potassium, should be monitored. This is especially important in the elderly. 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.

Contra-Indications

Do not use if you are hypersensitive to the active substance (sennosides) or to any ingredient in the formulation; have an acute surgical abdomen; abnormal constrictions of the gastrointestinal tract; potential or existing intestinal blockage 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 and severe dehydration with depleted water or electrolytes.

Known Adverse Reactions

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 pathological 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 adverse reactions listed below are classified according to their incidence (common or uncommon). Common adverse reactions have an incidence of = 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.

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.

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