

NATURAL HEALTH PRODUCT

SENNA – *SENNA ALEXANDRINA*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

December 18, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Senna alexandrina</i>	<ul style="list-style-type: none"> ▶ Alexandrian senna ▶ Indian senna ▶ Senna ▶ Tinnevelly senna ▶ True senna 	<i>Senna alexandrina</i>	<ul style="list-style-type: none"> ▶ Fruit ▶ Fruit and leaf ▶ Leaf 	Dried

Références: Proper name: USDA 2018; Common names: USDA 2018, EMEA 2006a,b, McGuffin 2000; Source materials: EMEA 2006a,b.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.



Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- ▶ (Traditionally used in Herbal Medicine as a) stimulant laxative (Sweetman 2007; Williamson 2003; Blumenthal et al. 2000; Felter and Lloyd 1983).
- ▶ (Used in Herbal Medicine for the) short-term relief of occasional constipation (EMEA 2006a,b; Mills and Bone 2005; ESCOP 2003; WHO 1999).
- ▶ (Used in Herbal Medicine to) promote(s) bowel movement (by direct action on the large intestine) (Sweetman 2007; Pray 2006; McGuffin et al. 1997).

The following combined use(s) or purpose(s) is/are also acceptable:

(Used in Herbal Medicine as a) stimulant laxative to promote bowel movement and short-term relief of occasional constipation (EMEA 2006a,b; Sweetman 2007; Pray 2006; Mills and Bone 2005; Williamson 2003; Blumenthal et al. 2000; WHO 1999; McGuffin et al. 1997; Felter and Lloyd 1983).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adolescents 12 to 17 years and Adults 18 years and older (Mills and Bone 2005; ESCOP 2003; WHO 1999)

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

0.5 - 3 grams of dried fruit and/or leaf, per day (Mills and Bone 2005; Williamson 2003; Blumenthal et al. 2000; WHO 1999; McGuffin et al. 1997; Felter and Lloyd 1983).

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

15 - 30 milligrams of sennoside B (i.e. hydroxyanthracene derivatives calculated as sennoside B), per day (EMEA 2006a,b; Mills and Bone 2005).



Direction(s) for use

- ▶ Take two to three times per week. If results are not observed, the frequency of use may be increased up to once daily (EMEA 2006a,b).
- ▶ Take a single dose at bedtime (EMEA 2006a,b; ESCOP 2003; WHO 1999).
- ▶ Take a few hours before or after taking other medications or natural health products (Brinker 2010; Repchinsky et al. 2005).
- ▶ Allow at least 6 to 12 hours for laxative effect to occur (EMEA 2006a,b; Berardi et al. 2002).

Products providing a dosage range (Optional)

The correct individual dose is the smallest required to produce a soft-formed stool (EMEA 2006a,b; ESCOP 2003; Blumenthal et al. 2000; WHO 1999).

Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 7 days (Berardi et al. 2002).

Risk information

Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a kidney disorder, faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever (Brinker 2010; EMEA 2006a,b; Blumenthal et al. 2000; WHO 1999).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking cardiac medications such as cardiac glycosides or antiarrhythmic medications, thiazide diuretics, corticosteroids, licorice root or other medications or health products which may aggravate electrolyte imbalance (Brinker 2010; EMEA 2006a,b; Blumenthal et al. 2000; WHO 1999).
- ▶ Reduce dose or stop use if you experience abdominal pain, cramps, spasms and/or diarrhoea (EMEA 2006a,b; Blumenthal et al. 2000; WHO 1999; McGuffin et al. 1997).

Contraindication(s)

- ▶ Do not use this product 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, severe dehydration with depleted water or electrolytes or diarrhoea (Brinker 2010; EMEA 2006a,b; WHO 1999; McGuffin et al. 1997).



- ▶ Do not use this product if you are pregnant or breastfeeding (Brinker 2010; EMEA 2006a,b; Blumenthal et al. 2000; McGuffin et al. 1997).

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (EMEA 2006a,b).

Non-medicinal ingredients

Must be chosen from the current Natural Health Product Ingredient Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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