Senna

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SENNA - SENNA ALEXANDRINA Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 105 KB) 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 July 26, 2024 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation Senna alexandrina Alexandrian senna Indian senna Senna Tinnevelly senna True senna Senna alexandrina Fruit Fruit and leaf Leaf Dry Références: Proper name: USDA 2024; Common names: USDA 2024; EMA 2018a,b; Gardner and McGuffin 2013; Source information: EMA 2018a,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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. 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 (EMA 2018a,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). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Used in Herbal Medicine as a stimulant laxative for short-term relief of occasional constipation). For multi-ingredient products To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g. Senna is traditionally used in Herbal Medicine as a stimulant laxative). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required Dose(s) Subpopulation(s) Adolescents 12-17 years and Adults 18 years and older (Mills and Bone 2005; ESCOP 2003; WHO 1999) Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 0.5 - 3 grams of dried fruit and/or leaf, per day; and providing at least 0.5 g of dried fruit and/or leaf per single dose (Mills and Bone 2005; Williamson 2003; Blumenthal et al. 2000; WHO 1999; Felter and Lloyd 1983). Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 15 - 30 milligrams of sennoside B (i.e. hydroxyanthracene derivatives calculated as sennoside B), per day; and providing at least 15 mg of sennoside B (i.e. hydroxyanthracene derivatives calculated as sennoside B) per single dose (EMA 2018a,b; Mills and Bone 2005). Direction(s) for use Start with 1 dose, 2 to 3 times per week and increase up to once daily if results are not observed (EMA 2018a,b; ESCOP 2003; WHO 1999). Take a few hours before or after taking other medications or health products (Brinker 2010; Repchinsky et al. 2005). Allow at least 6 to 12 hours for laxative effect to occur (EMA 2018a,b; Berardi et al. 2002). Stimulant laxatives should only be used if occasional constipation cannot be improved by a change of diet or the administration of bulk forming laxatives (EMA 2018a,b). Optional (for products which provide a dosage range) The optimal dosage is the smallest dose required to produce a soft-formed stool (EMA 2018a,b; ESCOP 2003; Blumenthal et al. 2000; WHO 1999). Duration(s) of use Ask 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) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a kidney disorder or a lazy bowel (EMA 2018a,b; Brinker 2010; Blumenthal et al. 2000; WHO 1999). Ask a health

care practitioner/health care provider/health care professional/doctor/physician before use if you are taking heart medications, corticosteroids, diuretics, or other health products that may contribute to electrolyte imbalance (EMA 2018a,b; Brinker 2010; Blumenthal et al. 2000; WHO 1999). Contraindication(s) Do not use if you are pregnant or breastfeeding (EMA 2018a,b; Brinker 2010; Blumenthal et al. 2000). Do not use if you have inflammatory bowel disease, fever or any undiagnosed gastrointestinal trouble (EMA 2018a,b; Gardner and McGuffin 2013; Brinker 2010; WHO 1999). Known adverse reaction(s) Stop use if hypersensitivity/allergy or diarrhoea occurs (EMA 2018a,b; Blumenthal et al. 2000; WHO 1999). Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Blumenthal M, Goldberg A, Brinkmann J, éditeurs. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. EMA 2018a: European Medicines Agency. Community Herbal Monograph on Cassia Senna L., fructus and Cassia angustifolia Vahl, fructus. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 25 September 2018. [Accessed 2024 January 10]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/final-european-union-herbal-monograph-senna-alexandrina-mill-cassia-senna-l-cassia-angustifolia-vahl-fructus-revision-1_en.pdf EMA 2018b: European Medicines Agency. Community Herbal Monograph on Cassia senna L. and Cassia angustifolia Vahl, folium. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 12 January 2018. [Accessed 2024 January 10]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/draft-european-union-herbal-monograph-senna-alexandrina-mill-cassia-senna-l-cassia-angustifolia-vahl-folium-revision-1_en.pdf ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003. Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Gardner Z, McGuffin M. editors. 2013. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. Boca Raton (FL): CRC Press. Mills S, Bone K. 2005. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. Pray WS. Non-Prescription Product Therapeutics, 2nd edition. New York (NY): Lippincott Williams & Wilkins; 2006. Repchinsky C, Welbanks L, Bisson R, Bhalla A, Dang T, Fortin K, et al., editors. Compendium of Pharmaceuticals and Specialties. The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2005. Sweetman SC, editeur. Martindale : The Complete Drug Reference, 35th edition. London (UK) : Pharmaceutical Press; 2007 USDA 2024: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 January 10]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch WHO 1999: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 1. Geneva (CH): World Health Organization; 1999. Wichtl M, Anton R, editors. Therapeutic plants : Tradition, officinal practice, science and therapeutics, 2nd edition. Paris (F) : Lavoisier; 2003. Williamson EM. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use. Saffron Walden (UK): The C.W. Daniel Company Limited; 2003. References Reviewed Bradley PR, editor. 1992. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (GB): British Herbal Medicine Association. Ellingwood F. 1983. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications [Reprint of 1919 original]. HC 2009. Health Canada. TPD/NHPD Category IV Labelling Standard, Stimulant Laxatives. Ottawa (ON): Therapeutic Products Directorate, Health Canada. [Accessed 2024 January 10]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/nonprescription-drugs-labelling-standards/stimulant-laxatives-labelling-standards-non-prescription-drugs.html Moerman DE. 1998. Native American Ethnobotany. Portland (OR): Timber Press. Wiersema J, León B. 1999. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a kidney disorder or a lazy bowel (EMA 2018a,b; Brinker 2010; Blumenthal et al. 2000; WHO 1999).Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking heart medications, corticosteroids, diuretics, or other health products that may contribute to electrolyte imbalance (EMA 2018a,b; Brinker 2010; Blumenthal et al. 2000; WHO 1999). Contraindication(s) Do not use if you are pregnant or breastfeeding (EMA 2018a,b; Brinker 2010; Blumenthal et al. 2000).Do not use if you have inflammatory bowel disease, fever or any undiagnosed gastrointestinal trouble (EMA 2018a,b; Gardner and McGuffin 2013; Brinker 2010; WHO 1999). Known adverse reaction(s) Stop use if hypersensitivity/allergy or diarrhoea occurs (EMA 2018a,b; Blumenthal et al. 2000; WHO 1999).

NON-MEDICINAL INGREDIENTS

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

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

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.

REFERENCES

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002.Blumenthal M, Goldberg A, Brinkmann J, éditeurs. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000.Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.EMA 2018a: European Medicines Agency. Community Herbal Monograph on Cassia Senna

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Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation		
Senna alexandrina	Alexandrian sennaIndian sennaSennaTinnevelly sennaTurnera	Senna alexandrina	FruitFruit and leafLeaf	Dr