Cascara Sagrada

CASCARA SAGRADA - FRANGULA PURSHIANA 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 - 60.1 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 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 on the label. Date May 30, 2025 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(s) Frangula purshiana Bitter bark California buckthorn Cascara Cascara buckthorn Cascara sagrada Chittambark Chittem bark Sacred bark Western buckthorn Frangula purshiana Aged bark Dry References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Source information: Wichtl 2004; Blumenthal et al. 2000. 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 (Williamson 2003; Blumenthal et al. 2000; Moerman 1998; Felter and Lloyd 1983). (Used in Herbal Medicine for the) short-term relief of occasional constipation (EMA 2020; Mills and Bone 2005; WHO 2002). (Used in Herbal Medicine to) promote(s) bowel movement (by direct action on the large intestine) (EMA 2020; Sweetman 2007; Blumenthal et al. 2000). 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. Cascara 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 to 17 years and Adults 18 years and older (EMA 2020; Mills and Bone 2005; ESCOP 2003; Berardi et al. 2002) Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 0.25 - 3 grams of dried aged bark, per day; and providing at least 0.25 g of dried aged bark per single dose (Mills and Bone 2005, ESCOP 2003; Williamson 2003; WHO 2002; Blumenthal et al. 2000; Bradley 1992). Methods of preparation: Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 10 - 30 milligrams of hydroxyanthracene derivatives (calculated as cascaroside A), per day; and providing at least 10 mg of hydroxyanthracene derivatives (calculated as cascaroside A) per single dose (EMA 2020; Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000). 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 2020; Bradley 1992). Take a few hours before or after taking other medications or health products (Brinker 2010; Repchinsky 2008). Allow at least 6 to 12 hours for laxative effect to occur (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 2020). Optional (for products which provide a dosage range) The optimal dosage is the smallest dose required to produce a soft-formed stool (EMA 2020). 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 2020; Brinker 2010; WHO 2002). 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 2020; Brinker 2010; WHO 2002; Blumenthal et al. 2000). Contraindication(s) Do not use if you are pregnant or breastfeeding (EMA 2020; Brinker 2010; Blumenthal et al. 2000). Do not use if you have inflammatory bowel disease, fever or any undiagnosed gastrointestinal trouble (EMA 2020; Brinker 2010; WHO 2002). Known adverse reaction(s) Stop use if hypersensitivity/allergy or diarrhea occurs (EMA 2020; Brinker 2010). 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. Bark must be dried and aged for a minimum of one year or heated and dried to induce artificial aging to allow oxidation of the anthrones. For example, the bark may be heated in hot air at 80-100°C for several hours (Wichtl 2004; Blumenthal et al. 2000). 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, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (UK): British Herbal Medicine Association; 1992. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. EMA 2020. European Medicines Agency. Community Herbal Monograph on Rhamnus Purshianus D.C., cortex. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 15 January 2020. [Accessed 2024 January 12]. Available from: https://www.fitoterapia.net/archivos/201811/final-community-herbal-monograph-rhamnus-purshianus-dc-cortex_en.pdf?1 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. and McGuffin M. editors. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. American Herbal Products Association. Boca Raton (FL): CRC Press; 2013. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Moerman DE. Native American Ethnobotany. Portland (OR): Timber Press; 1998. Repchinsky C, editor. Compendium of Pharmaceuticals and Specialties. The Canadian Drug Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association; 2008. Sweetman SC, editor. 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 June 17]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch WHO 2002: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 2. Geneva (CHE): World Health Organization; 2002. Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2004. 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 Barnes J, Anderson LA, Philipson JD. Herbal Medicines: A Guide for Healthcare Professionals, 2nd edition. London (UK): The Pharmaceutical Press; 2002. BHP 1996: British Herbal Pharmacopoeia. Bournemouth (UK): British Herbal Medicine Association; 1996. BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983. Ellingwood F. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1919 original]. FDA 1985: Unites States Food and Drug Administration. Laxative Drug Products for Over-the-Counter Human Use; Tentative Final Monograph. Proposed Rules sections 334.10 and 334.52. Federal Register Volume 50, Number 10, Tuesday, January 15, 1985. [Accessed 2008 July 31]. Available from: http://www.fda.gov/cder/otcmonographs/category_sort/laxative.htm Gruenwald J, Bendler T, Jaenicke C, editors. PDR for Herbal Medicines, 3rd edition. Montvale (NJ): Medical Economics Company; 2004. Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003. Mills S, Bone K. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000. Pray WS. Non-Prescription Product Therapeutics, 2nd edition. New York (NY): Lippincott Williams & Wilkins; 2006. Repchinsky Canadian Pharmacists Association. Patient Self-Care. Helping Patients Make Therapeutic Choices. Ottawa (ON): Canadian Pharmacists Association; 2002. Wiersema J, León B. World Economic Plants:

A Standard Reference. Boca Raton (FL): CRC Press LLC; 1999. 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 2020; Brinker 2010; WHO 2002).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 2020; Brinker 2010; WHO 2002; Blumenthal et al. 2000). Contraindication(s) Do not use if you are pregnant or breastfeeding (EMA 2020; Brinker 2010; Blumenthal et al. 2000).Do not use if you have inflammatory bowel disease, fever or any undiagnosed gastrointestinal trouble (EMA 2020; Brinker 2010; WHO 2002). Known adverse reaction(s) Stop use if hypersensitivity/allergy or diarrhea occurs (EMA 2020; Brinker 2010).

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 theNatural Health Products Regulations.

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.Bark must be dried and aged for a minimum of one year or heated and dried to induce artificial aging to allow oxidation of the anthrones. For example, the bark may be heated in hot air at 80-100°C for several hours (Wichtl 2004; Blumenthal et al. 2000). EXAMPLE OF PRODUCT FACTS:

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Frangula purshiana	Bitter barkCalifornia buckthornCascaraCascara buckthornCascara sagradaChittem barkChittenbarkSacred b			