Hawthorn

Source: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=crataegus.monogyna(=eng

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Natural Health Product Hawthorn (PDF Version - 51.3 KB) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. Note 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 the statements are synonymous. Either term or statement may be selected by the applicant. Date July 30, 2021 Proper and common name(s), Source information Table 1: Proper and common name(s), Source information Proper name(s) Common name(s) Source material(s) Source material(s) Part(s) Preparation(s) Crataegus laevigata English hawthorn Hawthorn Maytree Two-style hawthorn Whitethorn Woodland hawthorn Crataegus laevigata Fruit Flower and leaf Dried Crataegus monogyna Hawthorn Oneseed hawthorn One-style hawthorn Crataegus monogyna References: Proper names: USDA 2019; Common names: Wichtl 2004, McGuffin et al. 2000; Source information: ESCOP 2009, Barnes 2007, Bradley 2006, Belz and Loew 2003, Degenring et al. 2003, ESCOP 2003, Mills and Bone 2000, WHO 1999, Grieve 1971. Route Of Administration Oral (ESCOP 2009; Bradley 2006; Mills and Bone 2000) 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) Fruit (Traditionally) used in Herbal Medicine to help maintain and/or support cardiovascular health in adults (ESCOP 2009; Bradley 2006; Wichtl 2004; Degenring et al. 2003; ESCOP 2003; Mills and Bone 2000; WHO 1999; Grieve 1971). Flower and leaf Used in Herbal Medicine to help maintain and/or support cardiovascular health in adults (Bradley 2006; Wichtl 2004; ESCOP 2003; Mills and Bone 2000; WHO 1999). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 1 Fruit Traditional Herbal Medicine and Herbal Medicine claims (non-traditional) Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 0.6-3.5 g dried fruit, per day (ESCOP 2009; Bradley 2006; Degenring et al. 2003; Grieve 1971) Herbal Medicine claim (non-traditional) Methods of preparation: Standardized ethanolic extracts (Dry extract) 300 - 750 milligrams of extract, per day, standardized to 0.9 - 10% of Oligomeric proanthocyanidins (OPC) (Godfrey and Saunders 2010 Degenring 2003). Flower and leaf Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 1.5-5 grams of dried flower and leaf, per day (Bradley 2006; ESCOP 2003) Methods of preparation: Standardized ethanolic extracts (Dry extract) 160-900 milligrams of extract, per day, standardized to 18.75% of Oligomeric procyanidins, as epi-catechin, and/or to 2.2% of flavonoids, as hyperoside (Blumenthal et al. 2000; WHO 1999). Note 1 If both Crataequs species are used in a product formulation, the total amount of fruit, flower and leaf or standardized extract should be within the quantity ranges listed on the monograph. Direction(s) for use No statement required Duration of use Use for at least two months to see beneficial effects (Mills and Bone 2000) 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 are taking cardiac glycosides such as digitalis/digoxin, or blood pressure medication (Brinker 2010; Bradley 2006) Contraindication(s): No statement required. Known adverse reaction(s): No statement required. Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) View 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 (NHPR). Specifications The finished product specification 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 cited Belz GG, Loew D. 2003. Dose-response related efficacy in orthostatic hypotension of a fixed combination of D-camphor and an extract from fresh Crataegus berries and the contribution of the single components. Phytomedicine 10(Supplement 4):61-67. Blumenthal M, Goldberg A, Brinkmann J, editors. 2000.

Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications. Bradley PR, editor. 2006. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association. Brinker F. 2010. Updates and Additions for Herbal Contraindications and Drug Interactions plus Herbal Adjuncts with Medicines, 4 th edition. Eclectic Medical Publications. [Accessed 2019 June 261. Available https://www.eclecticherb.com/herb-contraindications-drug-interactions Degenring FH, Suter A, Weber M, Saller R. 2003. A randomised double blind placebo controlled clinical trial of a standardised extract of fresh Crataegus berries (Crataegisan) in the treatment of patients with congestive heart failure NYHA II. Phytomedicine 10(5):363-369. ESCOP 2009: European Scientific Cooperative on Phytotherapy Scientific Committee. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition, Supplement 2009. Exeter (GB): European Scientific Cooperative on Phytotherapy in collaboration with Thieme. ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy in collaboration with Thieme. Godfrey A, Saunders PR, Barlow K, Gilbert C, Gowan M, Smith F. Principles and Practices of Naturopathic Botanical Medicine. Volume 1: Botanical Medicine Monographs. Toronto (ON): CCNM Press; 2010. Grieve M. 1971. A Modern Herbal, Volume 1. New York (NY): Dover Publications; [Reprint of 1931 Harcourt, Brace & Company publication]. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. Herbs of Commerce, 2 nd edition. Silver Spring (MD): American Herbal Products Association. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. Crataegus laevigata (Poir.) DC. Beltsville (MD): Resources Laboratory. [Accessed 2019 261. National Germplasm June Available grin.gov/gringlobal/taxon/taxonomysimple.aspx WHO 2002: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 2. Geneva (CH): World Health Organization. Wichtl M, editor. 2004. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3 rd edition. Stuttgart (DE): Medpharm GmbH Scientific Publishers. References reviewed Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3 rd edition. London (GB): The Pharmaceutical Press. BP 2008: British Pharmacopoeia Commission. British Pharmacopoeia 2009, Volume III. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA). Brinker F. 2001. Herb Contraindications and Drug Interactions, 3 rd edition. Sandy (OR): Eclectic Medical Publications. Ellingwood F. 1998. American Materia Medica, Therapeutics and Pharmacognosy, Sandy (OR): Eclectic Medical Publications; [Reprint of 1919 original]. Felter HW, Lloyd JU. 1983. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; [Reprint of 1898 original]. HC 2010. Health Canada. Draft Guidance Document: Schedule A and Section 3 to the Food and Drugs Act . July 23, 2008 [online]. Ottawa (ON): Bureau of Policy, Science and International Programs, Therapeutic Products Directorate; Health Products and Food Branch. [Accessed: 2010 March 04]. Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press. JC 2008: Department of Justice Canada. Natural Health Products Regulations [online]. Ottawa (ON): Department of Justice Canada. [Accessed 2008 March 28]. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press. Ph. Eur. 2007: European Pharmacopoeia Commission. European Pharmacopoeia 2008, 6th edition, Volume 2. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), USP 2009: The United States Pharmacopeia and the National Formulary (USP 32/NF 27). Rockville (MD): United States Pharmacopeial Convention, Inc. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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

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): 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 are taking cardiac glycosides such as digitalis/digoxin, or blood pressure medication (Brinker 2010; Bradley 2006) Contraindication(s): No statement required. Known adverse reaction(s): No statement required.

NON-MEDICINAL INGREDIENTS

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

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).

SPECIFICATIONS

The finished product specification 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.

roper name(s)	Common name(s)	Source material(s)		
ource material(s)	Part(s)	Preparation(s)		
rataegus laevigata	English hawthornHawthornMaytreeTwo-styl	e Cantaleogus Valet iganta n Woodland h	avFithuottFlower and leaf	Dried
rataegus monogyna	HawthornOneseed hawthornOne-style hawt	h@mataegus monogyna		