

Witch Hazel - Hamamelis Virginiana Oral

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WITCH HAZEL - HAMAMELIS VIRGINIANA Oral 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 - 108 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 November 29, 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(s) Hamamelis virginiana Hamamelis Spotted alder Winter bloom Witchazel Witch-hazel Hamamelis virginiana Bark Leaf Dry References: Proper name: USDA 2024; Common names: Bradley 2006; ESCOP 2003, Gardner and McGuffin 2013; Source information: Bradley 2006; ESCOP 2003. 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) Back or Leaf (Traditionally) used in Herbal Medicine (as an astringent) to help relieve diarrhoea (Bradley 2006; Blumenthal et al. 2000; Ellingwood 1983; Grieve 1971). Leaf only (Traditionally) used in Herbal Medicine (as an astringent) to help relieve symptoms associated with varicose veins (such as painful and heavy legs) (ESCOP 2003; Hoffmann 2003; Felter 1983). Notes 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. Witch-hazel is traditionally used in Herbal Medicine to help relieve diarrhoea). 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) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Bark 0.6 - 9 grams of dried bark, per day (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000) Leaf 1.2 - 12 grams of dried leaf, per day (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000) *Note: Solvents allowed for the method of preparation "Non-Standardized Extracts (Dry extract)" as part of this monograph are ethanol and/or water only. Direction(s) for use Take a few hours before or after taking minerals and/or B-vitamin supplements (Brinker 2010; Mills and Bone 2000). Duration(s) of Use No statement required. 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 are pregnant or breastfeeding (Barnes et al. 2007; ESCOP 2003). Contraindication(s) No statement required Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Gardner and McGuffin 2013; ESCOP 2003; Berardi et al. 2002; Mills and Bone 2000). 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 Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3rd edition. London (GB): The Pharmaceutical Press. Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. 2002. Handbook of Nonprescription Drugs: An

Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association. 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. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Ellingwood F. 1983. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications [Reprint of 1919 original]. ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. 2003. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme. Felter HW. 1983. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications [Reprint of 1922 original]. Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. Second Edition. Boca Raton (FL): Taylor and Francis Group; 2013. Grieve M. 1971. A Modern Herbal, Volume 2. New York (NY): Dover Publications [Reprint of 1931 Harcourt, Brace & Company publication]. Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. USDA 2024: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 March 14]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> References reviewed BHP 1996: British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 1996. Bove M. 2001. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing, Incorporated. BP 2008: British Pharmacopoeia Commission. 2007. British Pharmacopoeia 2008, Volume 1. London (UK): The Stationary Office. BPC 1973: The British Pharmaceutical Codex. London (GB): The Pharmaceutical Press. EMA 2008. European Medicines Agency. Committee on Herbal Medicinal Products. Draft. Community Herbal Monograph on *Hamamelis virginiana* L., FOLIUM et CORTEX DESTILLATUM and *Hamamelis virginiana* L., RAMUNCULUS DESTILLATIUM. [Accessed 2024 March 14]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/draft-community-herbal-monograph-hamamelis-virginiana-l-folium-et-cortex-destillatum-hamamelis_en.pdf Felter HW, Lloyd JU. 1983. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications [Reprint of 1898 original]. McIntyre A. 2005. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited. Meyer JE. 1993. The Herbalist. Glenwood (IL): Meyerbooks. Mills S. 1993. The Essential Book of Herbal Medicine. Toronto (ON): Arkana. Mills S. 1985. The Dictionary of Modern Herbalism. Wellingborough (GB): Thorsons Publishers Ltd. Moerman DE. 1998. Native American Ethnobotany. Portland (OR): Timber Press. Schilcher H. 1997. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (DE): Medpharm Scientific Publishers. Sweetman SC, editor. 2007. Martindale: The Complete Drug Reference, 35th edition. London (GB): Pharmaceutical Press. Williamson EM. 2003. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use. Saffron Walden (GB): The C.W. Daniel Company Limited. Wren RC. 1907. Potter's Cyclopaedia of Botanical Drugs and Preparations. London (GB): Potter and Clark. Zeylstra H. 1998. *Hamamelis virginica*. British Journal of Phytotherapy 5(1):23-28. 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 are pregnant or breastfeeding (Barnes et al. 2007; ESCOP 2003). Contraindication(s) No statement required Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Gardner and McGuffin 2013; ESCOP

2003; Berardi et al. 2002; Mills and Bone 2000).

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 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

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Hamamelis virginiana	Hamamelis Spotted alder Winter bloom Witch hazel Hamamelis virginiana	Hamamelis Hamamelis virginiana	Bark Leaf	Dry