Witch Hazel - Hamamelis Virginiana Topical

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WITCH HAZEL - HAMAMELIS VIRGINIANA Topical 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 - 51.3 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 February 28, 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) Hamamelis virginiana Hamamelis Spotted alder Winter bloom Witchazel Witch-hazel Hamamelis virginiana Bark Leaf Dry Hamamelis virginiana Hamamelis water 1 Witch hazel water 1 Hamamelis virginiana Twig dormant Dry 2 References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013, Bradley 2006, ESCOP 2003; Source information: Bradley 2006, ESCOP 2003. 1 See dose section below for information on the method of preparation required to obtain Hamamelis/Witch hazel water. 2 Dry = partially dried as per the USP preparation. Route of Administration Topical Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Cream; Gel; Liquid; Loose; Lotion; Ointment; Paste; Powder; Salve; Solution; Topical liquid; Wipe. Use(s) or Purpose(s) Bark and/or Leaf (Traditionally) used in Herbal Medicine (as an astringent) to help treat varicose veins (Bradley 2006; Mills and Bone 2000; Felter 1983; Grieve 1971). Twig dormant (Hamamelis water) (Traditionally) used in Herbal Medicine (as an astringent) to help heal minor wounds, burns, bruises, irritations and local inflammations (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000; Felter 1983). (Traditionally) used in Herbal Medicine (as an astringent) to help relieve hemorrhoids (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000; Ellingwood 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 treat varicose veins). 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) Children 2-11 years, Adolescents 12-17 years, Adults 18 years and older (McIntyre 2005; Bove 2001; Schilcher 1997) Quantity(ies) Notes: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). For wipes, the quantity applies to the liquid with which wipes are saturated. Bark and leaf Loose/Powder dosage forms Methods of preparation: Dry, Powdered 100% dried bark and/or leaves (Blumenthal et al. 2000). Note: Products in loose or powder dosage forms must be prepared as a decoction by the consumer prior to use (see direction for use). Cream/Gel/Lotion/Liquid/Ointment/Paste/Salve/Solution/Topical liquid/Wipe dosage forms Methods of preparation: Non-Standardized Liquid Extracts (Decoction, Decoction concentrate, Fluid extract, Tincture) 2 - 100% dried bark and/or leaf extract preparation in the finished product (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000). Notes: The extract ratio must be between 1:1 and 1:50. The formulation must be prepared in a way which is equivalent to a quantity of 20 to 100 milligrams crude dried bark and/or leaf for 1 milliliter of finished product. For example, for a decoction prepared with a 1:10 w/w ratio, the concentration of decoction in the finished product must be 20 to 100% (20 - 100 mg crude dried bark and/or leaf * 10 w/w (dilution) = 200 - 1000 mg liquid extract in 1 mL finished product = 20 - 100% w/v extract preparation in the finished product). Twig dormant (Hamamelis water) Cream/Gel/Lotion/Ointment/Paste/Salve dosage forms Method of preparation: Distillation 20 - 30% of distillate (hamamelis water) in the finished product (Bradley 2006). Note: Hamamelis/Witch hazel water is prepared by macerating in water recently cut and partially dried

dormant twigs of Hamamelis virginiana in a ratio of 1:2 w/w (twigs:water) for 24 hours, and distilling twigs to a ratio of 1:0.80-0.85 w/v (twigs:distillate). To the distillate, 15% of ethanol (% of volume of finished product) is added. For example, 150 mL ethanol must be added to 850 mL distillate (USP-NF 2023). Liquid/Solution/Topical liquid/Wipe dosage forms Method of preparation: Distillation 30 - 100% of distillate (hamamelis water) in the finished product (Bradley 2006). Note: Products in liquid, solution and topical liquid dosage forms must be applied as a compress (see direction for use). Combination rule No permitted combinations between the two medicinal ingredients listed in Table 1. Direction(s) for use Loose/Powder dosage forms containing Hamamelis bark and/or leaf Place [insert volume to be measured by consumer in order to obtain 5 to 10 g dried leaf and/or bark, e.g., 1 teaspoon] of product in 250 mL of water, bring to a boil and simmer 10-15 minutes; let cool. Soak a small towel/pad/gauze/cotton in the product (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000). Liquid dosage forms (Liquid, Solution, Topical liquid) Soak a small towel/pad/gauze/cotton in the product (Bradley 2006). Products for use on varicose veins or minor wounds/burns/bruises/irritations/inflammations Apply to affected area(s), up to 4 times per day (Bradley 2006; Felter and Lloyd 1983). Products for use on hemorrhoids Cleanse the affected area with mild soap and warm water, rinse and dry. Apply to the affected area by patting gently (using a cleansing pad), up to 6 times daily (or after each bowel movement). Do not put this product into the rectum. Products which include a subpopulation of children 2 - 11 years of age Supervise children when they use this product. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All products For external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Products for use on minor wounds/burns/bruises/irritations/inflammations or on hemorrhoids Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen, last (for) more than 7 days. Products for use on varicose veins Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Products for use on minor wounds/burns/bruises/irritations/inflammations Do not use on deep or puncture wounds, animal bites or serious burns. Known adverse reaction(s) All products Stop use if a skin rash occurs (ESCOP 2003; Berardi et al. 2002; Mills and Bone 2000). Products for use on hemorrhoids Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience bleeding. 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, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. Bove M. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing, Incorporated; 2001. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association; 2006. ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme; 2003. Felter HW. 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Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 1996. Bove M. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing, Incorporated; 2001. BP 2008: British Pharmacopoeia Commission. British Pharmacopoeia, Volume 1. London (UK): The Stationary Office; 2008. BPC 1934: The British Pharmaceutical Codex. London (GB): The Pharmaceutical Press; 1934. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Ellingwood F. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1919 original]. 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 June 24]. 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. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003. McIntyre A. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited; 2005. Meyer JE. The Herbalist. Glenwood (IL): Meyerbooks; 1993. Mills S. The Essential Book of Herbal Medicine. Toronto (ON): Arkana; 1993. Mills S. The Dictionary of Modern Herbalism. Wellingborough (GB): Thorsons Publishers Ltd; 1985. Moerman DE. Native American Ethnobotany. Portland (OR): Timber Press; 1998. Schilcher H. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (DE): Medpharm Scientific Publishers; 1997. Williamson EM. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use. Saffron Walden (GB): The C.W. Daniel Company Limited; 2003. Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (GB): C.W. Daniel Company Limited; 1988. Wren RC. Potter's Cyclopedia of Botanical Drugs and Preparations. London (GB): Potter and Clark; 1907. Zeylstra H. Hamamelis virginia. British Journal of Phytotherapy 1998;5(1):23-28. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) All products For external use only.When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Products for use on minor wounds/burns/bruises/irritations/inflammations or on hemorrhoids Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen, last (for) more than 7 days. Products for use on varicose veins Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Products for use on minor wounds/burns/bruises/irritations/inflammations Do not use on deep or puncture wounds, animal bites or serious burns. Known adverse reaction(s) All products Stop use if a skin rash occurs (ESCOP 2003; Berardi et al. 2002; Mills and Bone 2000). Products for use on hemorrhoids Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience bleeding.

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. EXAMPLE OF PRODUCT FACTS:

REFERENCES

1See dose section below for information on the method of preparation required to obtain Hamamelis/Witch hazel water. 2Dry = partially dried as per the USP preparation. Route of Administration Topical

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Hamamelis virginiana	HamamelisSpotted alderWinter bloomWitch hazelWitch-hazel	Hamamelis virginiana	BarkLeaf	Dry
Hamamelis virginiana	Hamamelis water1Witch hazel water1	Hamamelis virginiana	Twig dormant	Dry2