

Witch Hazel - Hamamelis Virginiana Ophthalmic

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WITCH HAZEL - HAMAMELIS VIRGINIANA Ophthalmic 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 - 109 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 February 18, 2022 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 water 1 Witch Hazel water 1 Hamamelis virginiana Twig dormant Dry 2 References: Proper name: USDA 2019; Common names: Bradley 2006, ESCOP 2003, McGuffin et al. 2000; Source information: Bradley 2006, ESCOP 2003. 1 Hamamelis/Witch hazel water: macerate 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, distill twigs to a ratio of 1:0.80-0.85 w/v (twigs:distillate). To the distillate, add 14-15% of ethanol (% of volume of distillate) (USP 32). 2 Dry = partially dried as per the USP preparation. Route of Administration Ophthalmic Dosage Form(s) The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Liquid; Solution. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine for the temporary relief of eye discomfort due to dryness of the eye or to exposure to wind or sun (EMA 2008; Bradley 2006). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Adolescents 14-17 years and Adults 18 years and older (EMA 2008) Quantity(ies) Method of preparation: Distillation 10% of Hamamelis water 1 (EMA 2008) 1 Note One part Hamamelis water diluted with 10 parts sterile water (EMA 2008). Direction(s) for use Put 2 drops of diluted Hamamelis water in each eye, 3-6 times per day (EMA 2008). Duration(s) of Use Use for a maximum of 4 days (EMA 2008) 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. Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if you experience eye pain, changes in vision, continued redness, or irritation of the eye (EMA 2008). 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) 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 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 cited 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. 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 DESTILLATUM. [Accessed 2019 July 2]. 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 ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. 2003. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. Herbs of Commerce, 2 nd edition. Silver Spring (MD): American Herbal Products Association. USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. Hamamelis virginiana L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 July 2]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx> USP 32:

United States Pharmacopeial Convention. 2009. United States Pharmacopeia and the National Formulary (USP 32 - NF 27). Rockville (MD): The United States Pharmacopeial Convention. References reviewed 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. BHP 1996: British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 1996. Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications. 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 1934: The British Pharmaceutical Codex. London (GB): The Pharmaceutical Press. BPC 1973: The British Pharmaceutical Codex. London (GB): The Pharmaceutical Press. Brinker F. 2010. Updates and Additions for Herbal Contraindications and Drug Interactions plus Herbal Adjuncts with Medicines, 4th edition. Sandy (OR): Eclectic Medical Publications. [Accessed 2019 July 5]. Available from: <https://www.eclecticherb.com/herb-contraindications-drug-interactions> Brinker F. 2001. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications. Ellingwood F. 1983. 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]. 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. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press. 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, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. 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. Ph. Eur. 2008: European Pharmacopoeia Commission. 2007. European Pharmacopoeia, 6th edition, Volume 2. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM). 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. Williamson EM, Evans FJ, Wren RC. 1988. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (GB): 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 virginia. British Journal of Phytotherapy 5(1):23-28. 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) 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).

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. Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if you experience eye pain, changes in vision, continued redness, or irritation of the eye (EMA 2008). 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) 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).

STORAGE CONDITION(S)

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

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

1 Hamamelis/Witch hazel water: macerate 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, distill twigs to a ratio of 1:0.80-0.85 w/v (twigs:distillate). To the distillate, add 14-15% of ethanol (% of volume of distillate) (USP 32). 2 Dry = partially dried as per the USP preparation. Route of Administration Ophthalmic

| Proper name(s) | Common name(s) | Source information | | |
|----------------------|------------------------------------|----------------------|--------------|------|
| Source material(s) | Part(s) | Preparation(s) | | |
| Hamamelis virginiana | Hamamelis water1Witch Hazel water1 | Hamamelis virginiana | Twig dormant | Dry2 |