

Hops

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HOPS - HUMULUS LUPULUS 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 - 99 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 April 26, 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) Humulus lupulus Bine European hop Hop Hops Humulus lupulus Strobile Dry References: Proper name: USDA 2023; Common names: McGuffin et al. 2000, Bradley 1992; Source information: Mills and Bone 2005, Blumenthal et al. 2000, Bradley 1992. 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 to help relieve restlessness and/or nervousness (calmative) (EMA 2014; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Grieve 1971). (Traditionally) used in Herbal Medicine as a sleep aid (during times of mental stress) (EMA 2014; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Felter and Lloyd 1983). (Traditionally) used in Herbal Medicine as an aromatic bitter to aid digestion and to increase appetite (stomachic) (Mills and Bone 2005; Bradley 1992; Felter and Lloyd 1983; Grieve 1971). 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 to help relieve restlessness and/or nervousness and as a sleep aid during times of mental stress). 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. Hops is traditionally used in Herbal Medicine to help relieve restlessness and/or nervousness (calmative)). 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 12-17 years and Adults 18 years and older (EMA 2014; ESCOP 2003) Quantity(ies) Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Infusion) 0.5 - 6 grams of dried strobile, per day (EMA 2014; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992). *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 Sleep aid Take (1 hour) before bedtime, as needed (EMA 2014; Hoffmann 2003; Bradley 1992). Other uses No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Sleep aid Ask a health care practitioner/health care provider/health care professional/doctor/physician if sleeplessness persists continuously for more than 4 weeks (chronic insomnia) (Berardi et al. 2002; Dipiro et al. 2002). Other uses Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010; Barnes et al. 2007; Mills and Bone 2005; McGuffin et al. 1997). When using this product avoid taking with alcohol or products that cause drowsiness (Brinker 2010). When using this product exercise caution if you drive or use machinery as this product may cause drowsiness (EMA 2014). 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. 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. Herbal Medicines, 3rd edition. London (UK): The Pharmaceutical Press; 2007. 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, 13 th 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 Vol. 1. Bournemouth (UK): British Herbal Medicine Association; 1992. Brinker F. Herb Contraindications and Drug interactions, 4 th edition. Sandy (OR): Eclectic Medical Publications; 2010. Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: a pathophysiologic approach, 5th edition. New York (NY): The McGraw-Hill Companies, Inc.; 2002. EMA 2014: European Medicines Agency. Draft Community Herbal Monograph on Humulus lupulus L., Flos. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 6 May 2014. [Accessed 2023 September 14]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/final-community-herbal-monograph-humulus-lupulus-l-flos-revision-1_en.pdf ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003. Felten HW, Lloyd JU. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication]. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press; 1997. USDA 2023: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). Humulus lupulus L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2023 August 29]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx> References Reviewed Barnes J, Anderson LA, Philipson JD. Herbal Medicines: A Guide for Healthcare Professionals, 2nd edition. London (UK): The Pharmaceutical Press; 2002. BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983. Boon H, Smith M. The Botanical Pharmacy: The pharmacology of 47 Common Herbs. Kingston (Ontario): Quarry Press Inc.; 1999. Chevallier A. The Encyclopaedia of Medicinal Plants. New York (NY): Dorling Kindersley; 1996. Huang KC. The Pharmacology of Chinese Herbs. 2nd edition. Boca Raton (FL) CRC Press; 1999. Small E, Catling PM. Canadian Medicinal Crops. Ottawa (ON): National Research Council of Canada Monograph Publishing Program, NRC Research Press; 1999. Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2004. Wiersema J, Léon 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) Sleep aid Ask a health care practitioner/health care provider/health care professional/doctor/physician if sleeplessness persists continuously for more than 4 weeks (chronic insomnia) (Berardi et al. 2002; Dipiro et al. 2002). Other uses Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. All products Ask a health care

practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010; Barnes et al. 2007; Mills and Bone 2005; McGuffin et al. 1997).When using this product avoid taking with alcohol or products that cause drowsiness (Brinker 2010).When using this product exercise caution if you drive or use machinery as this product may cause drowsiness (EMA 2014).
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 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

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Humulus lupulus	BineEuropean hopHopHops	Humulus lupulus	Strobile	Dry