

NATURAL HEALTH PRODUCT

HOPS – *HUMULUS LUPULUS*

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

December 18, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Humulus lupulus</i>	<ul style="list-style-type: none"> ▶ Bine ▶ European hop ▶ Hop ▶ Hops 	<i>Humulus lupulus</i>	Strobile	Dried

References: Proper name: USDA 2018; Common names: McGuffin et al. 2000, Bradley 1992; Source material: 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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



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).

The following combined use(s) or purpose(s) is/are also acceptable:

(Traditionally) used in Herbal Medicine to help relieve restlessness and/or nervousness (calmative) and 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; Grieve 1971).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

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-Standardised 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)

Direction(s) for use

Sleep aid

Take one dose (1 hour) before bedtime (EMA 2014; Hoffmann 2003; Bradley 1992)

Duration(s) of use

No statement required.



Risk information

Caution(s) and warning(s)

Sleep aid

Consult 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).

All products

- ▶ 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 pregnant, breastfeeding or if you have depression and/or related diseases (Brinker 2010; Barnes et al. 2007; Mills and Bone 2005; McGuffin et al. 1997).
- ▶ Avoid taking with alcohol or products that cause drowsiness (Brinker 2010).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness (EMA 2014).

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

No statement required.

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

- 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, 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.
- Bradley PR, editor. British Herbal Compendium Vol. 1. Bournemouth (UK): British Herbal Medicine Association; 1992.
- Brinker F. Herb Contraindications and Drug interactions, 4th 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): EMEA Committee on Herbal Medicinal Products (HMPC), 6 May 2014. [Accessed 2018 September 28]. Available from: https://www.ema.europa.eu/documents/herbal-monograph/final-community-herbal-monograph-humulus-lupulus-l-flos_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.
- Felter 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 2018: 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 2018 September 28]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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.