

Valerian

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Valerian - VALERIANA OFFICINALIS 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 - 78 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 July 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) Valeriana officinalis Common valerian Garden-heliotrope Garden valerian Valerian Valeriana officinalis Root Root and rhizome Dry References: Proper name: USDA 2023; Common names: McGuffin et al. 2000; Source information: ESCOP 2003, Hoffmann 2003, BHP 1996. 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 2016; Mills and Bone 2005; Bradley 1992; Ellingwood 1983; Felter 1983). (Traditionally used in Herbal Medicine as a) sleep aid/(to) help(s) (to) promote sleep (Mills and Bone 2005; Ziegler et al. 2002; Blumenthal et al. 2000; Dominguez et al. 2000; Donath et al. 2000; Bradley 1992; Balderer and Borbély 1985; Leathwood and Chauffard 1985; Ellingwood 1983; Felter and Lloyd 1983; Leathwood et al. 1982). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Traditionally used in Herbal Medicine to help relieve restlessness and nervousness and to help promote sleep). 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. Valerian is traditionally used in Herbal Medicine as a sleep aid). 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, Infusion) 0.3-12 grams of dried root or root and rhizome, per day; Not to exceed 3.6 grams per single dose (EMA 2016; Mills and Bone 2005; Ziegler et al. 2002; Blumenthal et al. 2000; Donath et al. 2000; Bradley 1992; Balderer and Borbély 1985; Leathwood and Chauffard 1985; BHP 1983; Leathwood et al. 1982). *Note: Solvents allowed for the method of preparation "Non-standardized extracts (Dry extract)" as part of this monograph are ethanol and/or water only. Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 0.3-12 grams of dried root or root and rhizome, per day; Not to exceed 3.6 grams per single dose And: 0.05-0.90% valerenic acid (USP 2023; Brinker 2010) OR 0.10-0.90% sesquiterpenic acids (Brinker 2010; Ph. Eur. 2008) Note For extracts standardized to valerenic acid or sesquiterpenic acids, the quantity dried equivalent and the extract ratio must be provided. Direction(s) for use Sleep Aid Take 30 to 60 minutes before bedtime, as needed (Ziegler et al. 2002; Dominguez et al. 2000; Donath et al. 2000; Balderer and Borbély 1985; Leathwood and Chauffard 1985; Leathwood et al. 1982). Restlessness/nervousness No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All uses Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Mills et al. 2006; Blumenthal et al. 2003; Barnes et al. 2002). When using this product avoid taking with alcohol or products that cause drowsiness (Brinker 2010; Gennaro et al. 2000). When using this product exercise caution if you drive or use machinery as you may experience drowsiness (EMA 2016; ESCOP 2003; Bradley 1992). 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) (EMA 2016; Berardi et al. 2002; Dipiro et al. 2002). Restlessness/nervousness Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. 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 Balderer G, Borbély AA. 1985. Effect of valerian on human sleep. *Psychopharmacology* 87(4):406-409. Barnes J, Anderson LA, Phillipson JD. *Herbal Medicines: A guide for healthcare professionals*. 2nd ed. London (UK): Pharmaceutical Press; 2002. 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 1983: British Herbal Pharmacopoeia. Cowling (GB): British Herbal Medical Association. BHP 1996: British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association. Blumenthal M, Hall T, Goldberg A, Kunz T, Dinda K, Brinckmann J, Wollschlaeger B, editors. 2003. *The ABC Clinical Guide to Herbs: Valerian*. Austin, Texas: American Botanical Council. 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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.

DOSE(S)

Dorn M. 2000. [Efficacy and tolerability of Baldrian versus oxazepam in non-organic and non-psychiatric insomniacs: a randomized, double-blind, clinical, comparative study]. *Wirksamkeit und Verträglichkeit von Baldrian versus Oxazepam bei nichtorganischen und nichtpsychiatrischen Insomnien: Eine randomisierte, doppelblinde, klinische Vergleichsstudie*. *Forsch Komplementarmed Klass Naturheilkd* 7(2):79-84 (in German). Geller SE, Studee L. 2007. Botanical and dietary supplements for mood and anxiety in menopausal women. *The Journal of The North American Menopause Society* 14(3):541-549. ard U, Linnenbrink N, Georgiadou C, Hobi V. 1996. [Vigilance-decreasing effects of 2 plant-derived sedatives]. *Vigilanzmindernde Effekte zweier pflanzlicher Schlafmittel*. *Schweiz Rundsch Med Prax* 85(15): 473-481 (in German). Gooneratne NS. 2008. Complementary and alternative medicine for sleep disturbances in older adults. *Clinics in Geriatric Medicine* 24(1):121-138. Holst L, Nordeng H, Haavik S. 2008. Use of herbal drugs during early pregnancy in relation to maternal characteristics and pregnancy outcome. *Pharmacoepidemiology and Drug Safety* 17(2):151-159. JC 2018: Justice Canada. 2018. Food and Drug Regulations. (C.01.021) [online]. Ottawa (ON): Justice Canada; 2008. [Accessed 2018 December 19]. Available from: https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/FullText.html Kohnen W, Oswald WD. 1988. The effects of valerian, propranolol, and their combination on activation, performance, and mood of healthy volunteers under social stress conditions. *Pharmacopsychiatry* 21(6):447-448. Kuhlmann J, Berger W, Podzuweit H, Schmidt U. 1999. The influence of valerian treatment on "reaction time, alertness and concentration" in volunteers. *Pharmacopsychiatry* 32(6):235-241. Leathwood PD, Chauffard F. 1982/83. Quantifying the effects of mild sedatives. *Journal of Psychiatric Research* 17(2):115-122. Mayer B, Springer E. 1974. [Psychoexperimental studies on the effect of a valepotriate combination as well as the combined effects

of valtatum and alcohol]. Psychoexperimentelle Untersuchungen zur Wirkung einer Valepotriatkombination sowie zur kombinierten Wirkung von Valtratum und Alkohol. *Arzneimittelforschung* 24(12):2066-2070 (in German). McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press. 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. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. Miyasaka LS, Atallah AN, Soares BGO. 2008. Valerian for anxiety disorders. *Cochrane Database of Systematic Reviews* Issue 4. Art. No.:CD004515. DOI: 10.1002/14651858.CD004515.pub2. Morazzoni P, Bombardelli E. 1994. Valeriana officinalis: traditional use and recent evaluation of activity. *Fitoterapia* 66(2):99-112. Morin AK, Jarvis CI, Lynch AM. 2007. Therapeutic options for sleep-maintenance and sleep-onset insomnia. *Pharmacotherapy* 27(1):89-110. Oxman AD, Flottorp S, Håvelsrud K, Fretheim A, Odgaard-Jensen J, Austvoll-Dahlgren A, Carling C, Pallesen S, Bjorvatn B. 2007. A televised, web-based randomised trial of an herbal remedy (Valerian) for insomnia. *PLoS ONE* 2(10):e1040. Poyares DR, Guilleminault C, Ohayon MM, Tufik S. 2002. Can valerian improve the sleep of insomniacs after benzodiazepine withdrawal? *Progress in Neuro-Psychopharmacology & Biological Psychiatry* 26(3):539-545. Remington JP, Woods HC, editors. 1918. The Dispensatory of the United States of America [online] 20th edition. Abridged; botanicals only. Bisbee (AZ): Scanned by Michael Moore, director, The Southwest School of Botanical Medicine. [Accessed 2008 June 11]. Available from: <http://www.swsbm.com/Dispensatory/USD-1918-complete.pdf> Saeed SA, Bloch RM, Antonacci DJ. 2007. Herbal and dietary supplements for treatment of anxiety disorders. *American Family Physician* 76(4):549-556. Schilcher H. 1997. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (DE): medpharm Scientific Publishers. Schulz H, Jobert M, Hubner WD. 1998. The quantitative EEG as a screening instrument to identify sedative effects of single doses of plant extracts in comparison with diazepam. *Phytomedicine* 5(6):449-458. Schulz H, Stolz C, Müller J. 1994. The effect of valerian extract on sleep polygraphy in poor sleepers: a pilot study. *Pharmacopsychiatry* 27(4):147-151. Shimazaki M, Martin JL. 2007. Do herbal agents have a place in the treatment of sleep problems in long-term care? *Journal of the American Medical Directors Association* 8(4):248-252. Sood A, Sood R, Brinker FJ, Mann R, Loehrer LL, Wahner-Roedler DL. 2008. Potential for interactions between dietary supplements and prescription medications. *The American Journal of Medicine* 121(3):207-211. Taibi DM, Landis CA, Petry H, Vitiello MV. 2007. A systematic review of valerian as a sleep aid: safe but not effective. *Sleep Medicine Reviews* 11(3):209-230. Taibi DM, Vitiello MV, Barsness S, Elmer GW, Anderson GD, Landis CA. 2008. A randomized clinical trial of valerian fails to improve self-reported, polysomnographic, and actigraphic sleep in older women with insomnia. *Sleep Medicine* doi:10.1016/j.sleep.2008.02.001. Tariq SH, Pulisetty S. 2008. Pharmacotherapy for insomnia. *Clinics in Geriatric Medicine* 24(1):93-105. Tilgner S. 1999. Herbal Medicine from the Heart of the Earth. Creswell (OR): Wise Acre Press. Upton R, editor. 1999. American Herbal Pharmacopoeia and Therapeutic Compendium. Santa Cruz (CA): American Herbal Pharmacopoeia. Waldschütz R, Klein P. 2008. The homeopathic preparation Neurexan® vs. valerian for the treatment of insomnia: an observational study. *TheScientificWorldJOURNAL* 8:411-420. WHO 1999: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 1. Geneva (CHE): World Health Organization. Wiersema J, Léon B. 1999. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC. Williamson EM. 2003. Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medicinal 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.

RISK INFORMATION

Caution(s) and warning(s) All uses Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Mills et al. 2006; Blumenthal et al. 2003; Barnes et al. 2002). When using this product avoid taking with alcohol or products that cause drowsiness (Brinker 2010; Gennaro et al. 2000). When using this product exercise caution if you drive or use machinery as you may experience drowsiness (EMA 2016; ESCOP 2003; Bradley 1992). 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) (EMA 2016; Berardi et al. 2002; Dipiro et al. 2002). Restlessness/nervousness Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. 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.

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 EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details.

REFERENCES

Route of Administration Oral

Latin name(s)	Common name(s)	Source information	
Source material(s)	Part(s)	Preparation(s)	
Valeriana officinalis	Common valerianGarden-heliotropeGarden valerian	Valeriana officinalis	RootRoot and rhizome