

Skullcap

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SKULLCAP - SCUTELLARIA LATERIFLORA 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 - 72 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 November 29, 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) Scutellaria lateriflora Helmet flower Hoodwort Mad-dog skullcap Quarter bonnet Scullcap Skullcap Virginian skullcap Scutellaria lateriflora Herb top Dry References: Proper name: USDA 2023; Common names: McGuffin et al. 2000; Source information: Barnes et al. 2007. 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 (which helps to promote sleep) (nervine/calimative) (Bradley 2006; Boon and Smith 2004; Hoffmann 2003; Tilgner 1999; Williamson et al. 1988; Ellingwood 1983; Felter and Lloyd 1983). (Traditionally) used in Herbal Medicine to help relieve the pain associated with menstruation (antispasmodic) (Bradley 2006; Boon and Smith 2004; Mills and Bone 2000). Notes The recommended uses above can be combined on the product label if they are from the same traditional or non-traditional paradigm (e.g. Traditionally used in Herbal Medicine to help relieve restlessness, nervousness and pain associated with menstruation). 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. Skullcap is traditionally used in Herbal Medicine to help relieve nervousness). 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 Ethanolic Extracts (Dry extract, Tincture, Fluid extract) 0.25 - 12 grams of dried herb top, per day (Bradley 2006; Mills and Bone 2005; Boon and Smith 2004; Williamson et al. 1988; BHP 1983) Methods of preparation: Non-Standardized Aqueous Extracts (Dry extract, Decoction, Infusion) 3 - 12 grams of dried herb top, per day (Bradley 2006; Mills and Bone 2005; BHP 1983). Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) When using this product exercise caution if you drive or use machinery as you may experience drowsiness (Bradley 2006; Tilgner 1999; Williamson et al. 1988; Ellingwood 1983; Felter and Lloyd 1983). Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Do not use if you are pregnant or breastfeeding (Barnes et al. 2007; Boon and Smith 2004). Known adverse reaction(s) No statement required. Non-medicinal ingredients Must be chosen from the current Natural Health Product Ingredient 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, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Boon H, Smith MJ. The Complete Natural Medicine Guide to the 50 Most Common Medicinal Herbs, 2nd edition. Toronto (ON): Robert Rose Inc; 2004. BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (UK): British Herbal Medicine Association; 2006. 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. Ellingwood F. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1919 original]. Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Gennaro AR, editor. Remington: The Science and Practice of Pharmacy, 20th edition. Washington (DC): Lippincott Williams and Wilkins; 2000. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Mills S, Bone K. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000. Tilgner S. Herbal Medicine from the Heart of the Earth. Creswell (OR): Wise Acre Press; 1999. Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988. USDA 2023: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. [Accessed 2023 September 11]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> References Reviewed McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press; 1997. 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) When using this product exercise caution if you drive or use machinery as you may experience drowsiness (Bradley 2006; Tilgner 1999; Williamson et al. 1988; Ellingwood 1983; Felter and Lloyd 1983). Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) Do not use if you are pregnant or breastfeeding (Barnes et al. 2007; Boon and Smith 2004). Known adverse reaction(s) No statement required.

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Product Ingredient 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:

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Scutellaria lateriflora	Helmet flowerHoodwortMad-dog skullcapQuaker's hatScullcap	Scutellaria Scullcap	SkullcapVriginian skullcap	Dry