

NATURAL HEALTH PRODUCT

SKULLCAP – *SCUTELLARIA LATERIFLORA*

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>Scutellaria lateriflora</i>	<ul style="list-style-type: none"> ▶ Helmet flower ▶ Hoodwort ▶ Mad-dog skullcap ▶ Quarter bonnet ▶ Scullcap ▶ Skullcap ▶ Virginian skullcap 	<i>Scutellaria lateriflora</i>	Herb top	Dried

References: Proper name: USDA 2018; Common names: McGuffin et al. 2000; Source material: 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 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) (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 as a sleep aid (during times of mental stress) (Bradley 2006; Tilgner 1999; 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).

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) (Bradley 2006; Boon and Smith 2004; Hoffmann 2003; Tilgner 1999; Williamson et al. 1988; Ellingwood 1983; Felter and Lloyd 1983).

Note

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

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised 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-Standardised 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)

Sleep aid

Consult a health care practitioner/health care provider/health care professional/doctor/physician if sleeplessness persists 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.
- ▶ Avoid taking with alcohol or products that cause drowsiness (Brinker 2010; Gennaro 2000).

Contraindication(s)

Do not use this product if you are pregnant or breastfeeding (Barnes et al. 2007; Boon and Smith 2004).

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 (Bradley 2006; Tilgner 1999; Williamson et al. 1988; Ellingwood 1983; Felter and Lloyd 1983).

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

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

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USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Scutellaria lateriflora* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 October 1]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxonomydetail.aspx?id=33427>

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