

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 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)
<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	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/calorative) (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.

Product Facts
Medicinal ingredient in each capsule <i>Scutellaria lateriflora</i> (Skullcap – herb top) XX mg
Uses <ul style="list-style-type: none"> • Used in Herbal Medicine to help relieve restlessness and nervousness which helps to promote sleep. • Traditionally used in Herbal Medicine to help relieve the pain associated with menstruation.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites
Contains aspartame
Do not use if you are pregnant or breastfeeding.
When using this product exercise caution if you drive or use machinery as you may experience drowsiness.
Ask a health care practitioner if symptoms persist or worsen.
Directions
Adults 18 years and older: Take X capsule(s), X times a day.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹ This section can be removed from the table if the product contains no allergen or aspartame.

References cited

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