



NATURAL HEALTH PRODUCT

VALERIAN – *VALERIANA OFFICINALIS*

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)
<i>Valeriana officinalis</i>	<ul style="list-style-type: none"> • Common valerian • Garden-heliotrope • Garden valerian • Valerian 	<i>Valeriana officinalis</i>	<ul style="list-style-type: none"> • 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.

Product Facts
Medicinal ingredient in each capsule <i>Valeriana officinalis</i> (Valerian) (X:1 extract) XX mg Standardized to • 0.2% valerenic acid • 0.3% sesquiterpenic acids Equivalent to YY g dried root
Uses <ul style="list-style-type: none"> • Traditionally used in Herbal Medicine to help relieve restlessness and/or nervousness. • Helps to promote sleep.
Warnings If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame Ask a health care practitioner before use if you are pregnant or breastfeeding.
When using this product • avoid taking with alcohol or products that cause drowsiness • exercise caution if you drive or use machinery as you may experience drowsiness.
Ask a health care practitioner if • sleeplessness persists for more than 4 weeks (chronic insomnia) • symptoms persist or worsen (nervousness).
Directions Adults 18 years and older: Take X capsule(s), X times a day. Take 30 to 60 minutes before bedtime, as needed.
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.

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