

## 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

February 25, 2019

#### 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>Valeriana officinalis</i>	<ul style="list-style-type: none"> <li>▶ Common valerian</li> <li>▶ Garden-heliotrope</li> <li>▶ Garden valerian</li> <li>▶ Valerian</li> </ul>	<i>Valeriana officinalis</i>	<ul style="list-style-type: none"> <li>▶ Root</li> <li>▶ Root and rhizome</li> </ul>	Dried

References: Proper name: USDA 2018; Common names: McGuffin et al. 2000; Source materials: 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 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) (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).

### 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 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).

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:

- ▶ 0.04-0.90% valerenic acid (USP 2011; 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 (Optional)*

- ▶ Take a single dose 30 to 60 minutes before bedtime (Ziegler et al. 2002; Dominguez et al. 2000; Donath et al. 2000; Balderer and Borbély 1985; Leathwood and Chauffard 1985; Leathwood et al. 1982).
- ▶ Take an earlier dose during the evening if necessary (EMA 2016).

## **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 continuously for more than 4 weeks (chronic insomnia) (EMA 2016; Berardi et al. 2002; Dipiro et al. 2002).

#### *All uses*

- ▶ 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 et al. 2000).

### **Contraindication(s)**

No statement required.

### **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 (EMA 2016; ESCOP 2003; Bradley 1992).

## 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

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.

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