

NATURAL HEALTH PRODUCT

ASHWAGANDHA – *WITHANIA SOMNIFERA*

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>Withania somnifera</i>	<ul style="list-style-type: none"> ▶ Asgandh ▶ Ashwagandha ▶ Asvagandha ▶ Winter-cherry ▶ Withania 	<i>Withania somnifera</i>	Root	Dried

References: Proper name: USDA 2018; Common names: API 2001, McGuffin et al. 2000; Source material: API 2001.

Route of administration

Oral (API 2001)

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 Ayurveda as *Rasayana* (rejuvenative tonic) (Sukh Dev 2006; API 2001; Upton 2000).
- ▶ Traditionally used in Ayurveda to relieve general debility, especially during convalescence or old age (API 2001; Kapoor 2001).
- ▶ Traditionally used in Ayurveda as a sleep aid (Khare 2004; Upton 2000).
- ▶ Traditionally used in Ayurveda to balance aggravated *Vata* (nervine) (Kapoor 2001; Khory and Katrak 1999; Nadkarni 1954).
- ▶ Traditionally used in Ayurveda for memory enhancement (Sukh Dev 2006; Upton 2000; Nadkarni 1954).
- ▶ Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress (e.g. in case of mental and physical fatigue related to stress) (Winston and Maimes 2007; Bone 2003; Williamson 2002).

The following combined use(s) or purpose(s) is/are also acceptable:

Traditionally used in Ayurveda as a sleep aid and to balance aggravated *Vata* (nervine) (Khare 2004; Kapoor 2001; Upton 2000; Khory and Katrak 1999; Nadkarni 1954).

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)

Traditional Ayurvedic Claims

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

2 - 6 grams of dried root, per day (Williamson 2002; API 2001; Kapoor 2001; Nadkarni 1954).

Adaptogen

Methods of preparation: Dry, Powder, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

2.5 - 6.5 grams of dried root, per day (Winston and Maimes 2007; Bone 2003; Williamson 2002).



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 Uses

- ▶ Consult a healthcare practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (Upton 2000; McGuffin et al. 1997).
- ▶ Avoid taking with alcohol or products that cause drowsiness (Berardi et al. 2002; Gennaro et al. 2000; McGuffin et al. 1997).

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 (Berardi et al. 2002).

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.

References cited

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Khory RN, Katrak NN. Materia Medica of India and Their Therapeutics. Delhi (India): Komal Prakashan; 1999.

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Sukh Dev. Prime Ayurvedic Plant Drugs. Tunbridge Wells (UK): Anshan; 2005.

Upton R, editor. American Herbal Pharmacopoeia and Therapeutic Compendium: Ashwagandha Root (*Withania somnifera*) – Standards of Analysis, Quality Control, and Therapeutics. Santa Cruz (CA): American Herbal Pharmacopoeia; 2000.

USDA 2018: ARS, National Genetic Resources Program. Germplasm Resources Information Network (GRIN), *Withania somnifera*. National Germplasm Resources Laboratory, Beltsville, Maryland (MD). [Accessed 2018 December 17]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxonomydetail.aspx?id=102407>

Williamson EM, editor. Major Herbs of Ayurveda. London (UK): Churchill Livingstone; 2002.

Winston D, Maimes S. Adaptogens: Herbs for strength, stamina and stress relief. Rochester (VT): Healing Arts Press; 2007.