

NATURAL HEALTH PRODUCT

PASSIONFLOWER – *PASSIFLORA INCARNATA*

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>Passiflora incarnata</i>	<ul style="list-style-type: none"> ▶ Apricot-vine ▶ Maypop ▶ Maypop passionflower ▶ Passionflower 	<i>Passiflora incarnata</i>	Herb top	Dried

References: Proper name: USDA 2018, EMA 2014; Common names: USDA 2018, EMA 2014; Source material: EMA 2014.

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) (Godfrey and Saunders 2010; Wichtl 2004; Blumenthal et al. 2000; Felter and Lloyd 1983).
- ▶ (Traditionally) used in Herbal Medicine as a sleep aid (during times of mental stress) (EMA 2014; Felter and Lloyd 1983).

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) (EMA 2014; Godfrey and Saunders 2010; Wichtl 2004; Blumenthal et al. 2000; Felter and Lloyd 1983).

Note

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

Dose(s)

Subpopulation(s)

Adolescents 12-17 years and Adults 18 years and older (EMA 2014)

Quantity(ies)

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

0.25 - 8 grams of dried herb top, per day (EMA 2014).

Methods of preparation: Non-Standardised Aqueous Extracts (Dry extract, Decoction, Infusion)

1 - 8 grams of dried herb top, per day (EMA 2014).

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.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (EMA 2014).
- ▶ Avoid taking with alcohol or products that cause drowsiness (EMA 2014; Brinker 2010).

Contraindication(s)

No statement required.

Known adverse reaction(s)

- ▶ Stop use if hypersensitivity/allergy occurs (EMA 2014).
- ▶ Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness (EMA 2014).

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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DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: A Pathophysiological Approach, 5th edition. New York (NY): McGraw-Hill Co. Inc.; 2002

EMA 2014. European Medicines Agency. Community Monograph on. London (UK): EMEA Committee on Herbal Medicinal Products (HMPC), 20 September 2016. [Accessed 2018 October 1]. Available from: https://www.ema.europa.eu/documents/herbal-summary/passion-flower-summary-public_en.pdf

Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

Godfrey A, Saunders PR, Barlow K, Gilbert C, Gowan M, Smith F. Principles and Practices of Naturopathic Botanical Medicine, Volume 1: Botanical Medicine Monographs. Toronto (ON): CCNM Press; 2010.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Passiflora incarnata* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 October 1]. Available from: <https://npgsweb.arsgrin.gov/gringlobal/taxonomydetail.aspx?id=26977>

Wichtl M, editor. 2004. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers.

References reviewed

ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003.