

## PASSIONFLOWER

<b>Date:</b>	March 20, 2008
<b>Proper name(s):</b>	<i>Passiflora incarnata</i> L. (Passifloraceae) (EMEA 2007; USDA 2007)
<b>Common name(s):</b>	Passionflower (EMEA 2007; USDA 2007)
<b>Source material(s):</b>	Aerial parts (EMEA 2007)
<b>Route(s) of administration:</b>	Oral
<b>Dosage form(s):</b>	Those suited to the allowable route(s) of administration. This monograph is not intended to include food-like dosage forms such as bars, chewing gums or beverages.
<b>Use(s) or Purpose(s):</b>	Statement(s) to the effect of:  Traditionally used in Herbal Medicine as a sleep aid (in cases of restlessness or insomnia due to mental stress) (EMEA 2007)
<b>Dose(s):</b>	
<b>Subpopulation:</b>	Adults, and adolescents $\geq 13$ years (EMEA 2007)
<b>Quantity:</b>	Preparations equivalent to 0.25-8 g dried aerial parts, per day (EMEA 2007)  See Appendix 1 for examples of appropriate dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.
<b>Duration of use:</b>	No statement required.

**Risk information:** Statement(s) to the effect of:

**Caution(s) and warning(s):**

- ▶ Consult a health care practitioner if symptoms persist or worsen.
- ▶ Consult a health care practitioner if sleeplessness persists continuously for more than 3 weeks (chronic insomnia) (Berardi et al. 2002; DiPiro et al. 2002).
- ▶ Consult a health care practitioner prior to use if you are pregnant or breastfeeding (EMEA 2007).
- ▶ Consumption with alcohol, other medications or natural health products with sedative properties is not recommended (Brinker 2008; EMEA 2007).

**Contraindication(s):** No statement required.

**Known adverse reaction(s):**

- ▶ Hypersensitivity (e.g. allergy) has been known to occur; in which case, discontinue use (EMEA 2007).
- ▶ Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness (EMEA 2007).

**Non-medicinal ingredients:** Must be chosen from the current NHPD *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.

**Specifications:**

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ The medicinal ingredient may comply with the specifications outlined in the Passion Flower Monograph published in the British or the European Pharmacopoeias.

**References cited:**

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002.

Brinker F. Online Updates and Additions to Herb Contraindications and Drug Interactions, 3<sup>rd</sup> edition. Sandy (OR): Eclectic Medical Publications; 2008. [Accessed 2008-03-20]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

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

EMEA 2007. European Medicines Agency. Community Monograph on. London (UK): EMEA Committee on Herbal Medicinal Products (HMPC), 31 October 2007. [Accessed 2008-03-20]. Available from: [http://www.emea.europa.eu/pdfs/human/hmpc/passiflorae\\_herba/23096206enfin.pdf](http://www.emea.europa.eu/pdfs/human/hmpc/passiflorae_herba/23096206enfin.pdf)

USDA 2007: 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 2008-03-20]. Available from: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl)

### **References reviewed:**

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

**Appendix 1:** Examples of appropriate dosage preparations, frequencies of use and directions for use (EMEA 2007)

Dried aerial parts: 0.5-2 g, 1-4 times per day

Infusion: 1-2 g dried aerial parts, 1-4 times per day

**Directions for use:** Pour 150 ml of boiling water on dried aerial parts and steep for 10 minutes.

Fluidextract:

- ▶ 0.5-2 g dried equivalent, 1-4 times per day  
(1:1, 25% alcohol, 0.5-2 ml)
- ▶ 2 g dried equivalent, 1-3 times per day  
(1:1, 70% alcohol, 2 ml)

Tincture:

- ▶ 0.25-0.5 g dried equivalent, 1-4 times per day  
(1:8, 25% alcohol, 2-4 ml)
- ▶ 0.25 g dried equivalent, 1-3 times per day  
(1:8, 45% alcohol, 2 ml)