

## CHASTE TREE

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

**Note:** 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 are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

**Date:** June 9, 2010

**Proper name(s):** *Vitex agnus-castus* L. (Lamiaceae) (McGuffin et al. 2000; USDA 1998)

**Common name(s):**

- ▶ Chaste tree (McGuffin et al. 2000; USDA 1998)
- ▶ Chaste berry (McGuffin et al. 2000; USDA 1998)
- ▶ Vitex (Gilde des herboristes 2007; Passeport santé 2006)

**Source material(s):** Fruit/Berry (Blumenthal 2000; Mills & Bone 2000)

**Route(s) of administration:** Oral (WHO 2009; Bradley 2006; Mills and Bone 2000)

**Dosage form(s):** The acceptable pharmaceutical dosage forms include, but are not limited to, chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons. This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

**Use(s) or Purpose(s):** Statement(s) to the effect of:

- ▶ Used in Herbal Medicine to help relieve premenstrual symptoms (WHO 2009; Bradley 2006; Wichtl 2004; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000).

- ▶ Used in Herbal Medicine as a hormone normaliser to help stabilise menstrual cycle irregularities (WHO 2009; Bradley 2006; Wichtl 2004; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Mills and Bone 2000).
- ▶ Used in Herbal Medicine to help relieve symptoms associated with menopause, such as hot flushes (WHO 2009; Hoffmann 2003).

**Dose(s):** Preparations containing the equivalent of 30-2000 mg dried fruit, per day (WHO 2009; Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Mills and Bone 2000).

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.

**Duration(s) of use:** Statement(s) to the effect of:  
  
Use for a minimum of 3 month to see beneficial effects (Bradley 2006; ESCOP 2003; Hoffmann 2003).

**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 prior to use if you are taking hormone-containing medications such as progesterone preparations, oral contraceptives or hormone replacement therapy (Brinker 2010; WHO 2009; Bradley 2006).

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

**Known adverse reaction(s):** No statement required.

**Non-medicinal ingredients:** Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

**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 pharmacopoeial monographs listed in Table 1 below.

Table 1: Chaste tree Monographs published in the British (BP), European (Ph. Eur.) and United States (USP) Pharmacopoeias

| Pharmacopoeia  | Monograph                                                           |
|----------------|---------------------------------------------------------------------|
| BP<br>Ph. Eur. | Agnus Castus Fruit                                                  |
| USP            | Chaste Tree<br>Powdered Chaste Tree<br>Powdered Chaste Tree Extract |

**References cited:**

Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications.

Bradley PR, editor. 2006. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association.

Brinker F. 2010. Online Updates and Additions to Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications. [Updated 2010 February 15]; [Accessed 2010 March 04]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

BP 2009: British Pharmacopoeia Commission. 2008. British Pharmacopoeia 2009, Volume III. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA).

ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy in collaboration with Thieme.

Grieve M. 1971. A Modern Herbal, Volume 1. New York (NY): Dover Publications; [Reprint of 1931 Harcourt, Brace & Company publication].

Guilde des herboristes. 2007. Nomenclature d'herbes médicinales. Rapport d'experts pour la DPSN.

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press.

Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone.

PasseportSanté.net. 2007. Gattilier. [En ligne]. [Consulté le 12 mai 2010]. Disponible à : [http://www.passeportsante.net/fr/Solutions/PlantesSupplements/Fiche.aspx?doc=gattilier\\_ps](http://www.passeportsante.net/fr/Solutions/PlantesSupplements/Fiche.aspx?doc=gattilier_ps)

Ph. Eur. 2007: European Pharmacopoeia Commission. 2007. European Pharmacopoeia, 6th edition, Supplement 6.2. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM).

USDA 2006: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. *Vitex agnus castus* L. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2010 March 04]. 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)

WHO 2009: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 4. Geneva (CH): World Health Organization.

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

USP 2009: United States Pharmacopeial Convention. 2009. The United States Pharmacopeia and the National Formulary (USP 32/NF 27). Rockville (MD): United States Pharmacopeial Convention, Inc.

### References reviewed:

Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3rd edition. London (GB): The Pharmaceutical Press.

Brinker F. 2001. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications.

Ellingwood F. 1998. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; [Reprint of 1919 original].

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

Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press.

## Appendix 1: Examples of dosage preparations, frequencies of use and directions for use

### Fruit/berry:

For premenstrual symptoms:

Preparations equivalent to 30-240 mg of dried fruit, per day (ESCOP 2003)

For other use(s) or purpose(s):

Preparations equivalent to 30-40 mg of dried fruit, per day (ESCOP 2003)

### Fluidextract:

- ▶ 500-1000 mg dried equivalent, per day (1:1, 70% alcohol, 0.5-1.0 ml) (WHO 2009)
- ▶ 30-40 mg dried equivalent, per day (1:1, 50-70% alcohol, 0.03-0.04 ml) (Blumenthal et al. 2000)

### Tincture:

- ▶ 500 mg dried equivalent, per day (1:5, 58% ethanol, 2.5 ml) (WHO 2009)
- ▶ 40-240 mg dried equivalent, per day (Bradley 2006)
- ▶ 500 mg dried equivalent, 3 times per day (1:5, 60%, 2.5 ml) (Hoffmann 2004)
- ▶ 30-40 mg dried equivalent, per day (1:5, 50-70% alcohol, 0.15-0.2 ml) (Blumenthal et al. 2000)
- ▶ 200-1000 mg, per day (1:5, 1-5 ml) (Mills and Bone 2000)
- ▶ 500-2000 mg, per day (1:2, 1-4 ml) (Mills and Bone 2000)

### Tablet:

500 mg dried fruit, 1-2 tablets per day (Mills and Bone 2000)

### Dried extract:

Preparations equivalent to 40-240 mg of dried fruits, per day (50-70% ethanol) (Bradley 2006)